Supreme Court, U.S.
FILED

(1) 932052 JUN 9 1994

OFFICE OF THE CLERK

No.

IN THE
SUPREME COURT OF THE UNITED STATES

October Term, 1993

CONNIE ALBRECHT, et al.,

Petitioners,

v.

UNITED STATES DISTRICT COURT JUDGE
FOR THE NORTHERN DISTRICT OF ALABAMA
HONORABLE SAMUEL C. POINTER, JR., PRESIDING
AND McGHAN MEDICAL CORPORATION, et al.,

Respondents.

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

PETITION FOR WRIT OF CERTIORARI

ROBERT J. DEBRY
Counsel of Record
ROBERT J. DEBRY & ASSOCIATES
4252 South 700 East
Salt Lake City, UT 84107
(801) 262-8915
Counsel for Petitioners

102 pp

QUESTIONS PRESENTED

1. Is the Nuremberg Code part of due process constitutional law or federal common law?

2. Does a United States district court have a mandatory duty to provide notice and a meaningful hearing before denying a motion to certify a class action when, as in this case: a) all F.R.C.P. 23 requirements are apparently met; b) the court denies class action certification on a ground not specified in F.R.C.P. 23; and c) the proposed class representatives have no opportunity to address the reason identified by the district court for its decision denying class certification?

3. May mandamus be used to review and correct a defective class certification proceeding?

4. Does the district court have a mandatory duty to make and enter meaningful findings in support of its ruling denying class action certification?

LIST OF PARTIES AND RULE 29.1 STATEMENT

The parties to the proceedings below were the following petitioners:

Connie Albrecht;
Bonita Allgood;
Dorothy Anderson;
Claudia Archuleta;
Lynn Atherley;
Tamera Baker;
Mary Jane Balok;
Sally Barela;
Kathy Barnes;
Corrinne B; Beach;
Piper Beagley;
Linda Beaucannon;
Merlene Beheshti;
Barbara Bluemel;
Michelle Braithwaite;
Vera Burton;
Debra Cannon;
Carol Card;

Leslie Cheesman;
Raelynn Christensen;
Janice Connelly;
Shirlyn Cornwell;
Georgia Cragun;
Charlotte Crawford;
Roberta Crosgrove;
Mary Crozier;
Ann Cummins;
Jan Curnutt;
Julie Datwyler;
Judy Davison;
Jean Dickson;
Jane Does 1-12, 14-17;
Mae Dumas;
Carol Dunton;
Teresa Eastmond;
Sharon Ficklin;
Kathy Frazier;
Janet Gates;
Pat Gehring;
Peggy Genebach;
Sylvia Hansen;
Connie Hardcastle;
Sondra Harris;
Kerry Hill;
Jannette Hooley;
Mary Hualde;
Laraine Hunter;
Louise Hunter;
Sharon Jensen;
Jeri Johnson;
Maria Johnson;
Renae Johnson;
Lauri Jones;
Leda Jones;
Diann Joseph;
Connie Kaleel;
Carol Kendrick;
Julie Ketterer;
Ruth Leonard;
Dawn Lether;
Jenn Leydsman;
Candace Lish;
Kathy Litson;
Sandra D; Lund;
Rafaelita Martinez;
Annalee McGugin;
Ooma Menlove;
Teresa Mickelsen;
Kathy Nelson;
Sharon Nichols;
Sondra Nielsen;
Janice Oltersdorf;
Vicki Owens;
Kathy Peck;
Peggy Pendleton;
Kris Peterson;
Julie Pettersson;
Barbara J. Pledger;
Virginia Plowman;
Madalyn Ramos;
Sherion Reay;
Cindy Reimann;
Nedra Riley;
Brenda Riney;
Debra Robb;
Beckie Sanchez;
Liz Savage;
Brenda Scott;
Concilia Sipe;
Lavena Smith;
Janet Stewart;
Valois Strait;
Shirley Streeter;
Suzanne Stubbs;
Lisa Sutherland;
Helen Sweeney;

Dixie Taylor;
Tresa Taylor;
Trena Terry;
Carolyn Thompson;
Barbara Timmons;
Geraldine Vybiral;
Carol J. Waddoups;
Jana Wahler;
Pam Walker;
Michelle Weakland;
Lisa Westbury;
Janice White;
Agaytha Willis; and

the respondent is the United States District Court for the Northern District of Alabama, the Honorable Samuel C. Pointer, Jr. presiding.

Parent and subsidiary corporations in the underlying litigation are disclosed under Rule 29.1 of the Supreme Court of the United States as follows:

Dow Corning Corp.
Surgitek, Inc.
Medical Engineering Corp.
Bristol-Myers Squibb Co.
McGhan Medical Corp.
Inamed Corporation
Mentor Corporation
Heyer Schulte Corporation
American Hospital Supply
Baxter Healthcare Corp.
Baxter International, Inc.
Bioplasty, Inc.
Biomanufacturing, Inc.
CUI Corporation
Cox-Uphoff Corporation
Replicon Laboratories, Inc.
Natural Y Surgical Specialties, Inc.
Aesthetech Corporation
Cooper Companies
"21" International Holdings, Inc.
Wilshire Foam Products, Inc.
Sirod Corporation

TABLE OF CONTENTS

Page

QUESTIONS PRESENTED II

LIST OF PARTIES AND RULE 29.1 STATEMENT II

OPINION BELOW 2

JURISDICTION 2

CONSTITUTIONAL PROVISIONS, RULES AND STATUTES INVOLVED 2

STATEMENT OF THE CASE 3

ARGUMENT 7

I. WHETHER THE BASIC ETHICAL STANDARDS FOR HUMAN EXPERIMENTATION DECLARED BY THE NUREMBERG MEDICAL TRIALS IS INCLUDED WITHIN DUE PROCESS CONSTITUTIONAL LAW OR FEDERA COMMON LAW IS AN IMPORTANT QUESTION WHICH SHOULD BE DECIDED BY THIS COURT. 7

A. Summary of Argument. 7

B. Lower Court Proceedings. 8

C. Legal Analysis. 9

1. The Nuremberg Code. 9

2. Influence of the Nuremberg Code on federal law and regulations. 10

3. Why the Nuremberg Code issues justify judicial review. 13

a. Introduction 13

b. The breast implant litigation. 15

D. Other Human Experimentation. 17

II. CERTIORARI SHOULD BE GRANTED TO RESOLVE THE IMPORTANT ISSUE OF WHEN A UNITED STATES DISTRICT COURT MUST PROVIDE NOTICE AND AN OPPORTUNITY TO BE HEARD PRIOR TO DENYING A MOTION TO CERTIFY THE CLASS. 19

A. Summary of Argument 19

B. Proceedings in the Lower Court. 20

C. Legal Analysis. 20

1. Due process 20

2. Rule 23 21

3. Duty to manage the class action litigation. 21

III. THE RELATED ISSUES OF WHETHER MANDAMUS MAY BE USED TO REVIEW AND CORRECT CLASS ACTION CERTIFICATION PROCEEDINGS AND, IF SO, UNDER WHAT CIRCUMSTANCES, ARE IMPORTANT QUESTIONS OF FEDERAL LAW WHICH SHOULD BE DECIDED BY THIS COURT. . . . 22

A. Summary of Argument. 22

B. Proceeding Before the Lower Court 22

C. Legal Analysis. 22

IV. WHETHER A DISTRICT COURT HAS A DUTY TO MAKE MEANINGFUL FINDINGS IN SUPPORT OF AN ORDER DENYING CLASS CERTIFICATION IS AN IMPORTANT ISSUE WARRANTING CERTIORARI. 25

A. Summary of Argument. 25

B. Lower Court Proceedings. 25

C. Legal Analysis. 25

CONCLUSION 26

TABLE OF AUTHORITIES

Page

Cases

Bauman v. United States District Court, 557 F.2d 650 (9th Cir. 1977) 7, 23

Bradford v. Sears, Roebuck and Co., 673 F.2d 792 (5th Cir. 1982) 21, 22, 26

Commissioner v. Duberstein, 363 U.S. 278 (1959) 25

Eisen v. Carlisle, 417 U.S. 156 (1974) 19

Erie R. R. v. Tompkins, 304 U.S. 64 (1938) 13

Ezell v. Mobile Housing Board, 709 F.2d 1376 (11th Cir. 1983) 21

General Telephone Co. of Southwest v. Falcon, 457 U.S. 147 (1982) 19, 21

Heidi Lindsay v. et al. v. Dow Corning Corp., et al. Case No. CU-9UPP-11558-S 15

In re Bendectin Products Liability Litigation, 749 F.2d 300 (6th Cir. 1984) 24

In re Dalton, 733 F.2d 710 (10th Cir. 1984) 24

In re Temple, 851 F.2d 1269 (11th Cir. 1988) 20, 24

Kamowitz v. Michigan Dept. of Mental Health, Civ. No. 73-19434-AW (Mich. Cir. Ct. 1973) 13

Kerr v. United States District Court, 426 U.S. 394 (1976) 24

La Buy v. Howes Leather Co.,
352 U.S. 249 (1957) 20, 23, 24

Morrison v. Booth,
730 F.2d 642 (11th Cir. 1984) 20, 21

Pierce v. Ortho Pharmaceutical Corp.,
417 A.2d 505 (N.J. 1980) 13

Price v. Lucky Stores, Inc.,
501 F.2d 1177 (9th Cir. 1974) 26

Roche v. Evaporated Milk Ass'n,
319 U.S. 21 (1943) 23

Schlagenhauf v. Holder,
379 U.S. 104 (1964) 20, 22-24

Sirota v. Solitron Devices, Inc.,
673 F.2d 566 (2d Cir. 1982) 21

Strunck v. Strunk,
445 S.W.2d 145 (Ky. Ct. App. 1969) 13

Trials of War Criminals Before the Nuremberg
Military Tribunals under Control Council Law
No. 10 Vol. II (1946-1949) 8-10

United States v. Stanley,
483 U.S. 669 (1987) 3, 8, 12, 14

Whitlock v. Duke University,
637 F. Supp. 1463 (M.D.N.C. 1986) 13

Will v. United States,
389 U.S. 90 (1967) 23, 24

Constitutional Provisions

U.S. Const. amend. V 2

Statutes

21 U.S.C. § 360 15

28 U.S.C. § 1254 2

28 U.S.C. § 1291 22

28 U.S.C. § 1332 3

28 U.S.C. § 1407 3

28 U.S.C. § 1651 . . . . . 6, 23

Books and Articles

Andrew Ivy, "Nazi War Crimes of a Medical Nature," reprinted in Curran, Ethics in Medicine: Historical Perspectives and Contemporary Concerns, 270 (1977) 10

Ingersoll, "Amid Lax Regulation, Medical Devices Flood a Vulnerable Market," Wall Street J. (March 24, 1992) 16

Merrill, "The Common Law Power of Federal Courts", 52 U. of Chi. L. Rev. 1, 14-15 (Winter 1985) 14

Robert Drinan, "The Nuremberg Principles in International Law," in George Annas & Michael Grodin, eds., The Nazi Doctors and the Nuremberg Code 174 (1992) 9

U.S. v. Kark Brandt, et al., Trials if War Criminals Before the Nuremberg Military Tribunals Under Control Council Law No. 10, (1946-49), Vol. II. 9, 10

Miscellaneous

49 U.S. Dept. of Health, Education and Welfare, Health Volunteers Help Scientists Conquer Disease, PHS Pub. No. 714 at 14 (1959) (NIH) 11

Federal Rules of Civil Procedure, Rule 23 . . . . II, 2, 7, 19, 21

Federal Rules of Civil Procedure, Rule 52 . . . . . 2, 7, 25

Nuremberg Code 2

IN THE
SUPREME COURT OF THE UNITED STATES

October Term, 1994

No.

CONNIE ALBRECHT, et al.,

Petitioners,

v.

UNITED STATES DISTRICT COURT JUDGE
FOR THE NORTHERN DISTRICT OF ALABAMA
HONORABLE SAMUEL C. POINTER, JR., PRESIDING
AND McGHAN MEDICAL CORPORATION, et al.,

Respondents.

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

To the Honorable Chief Justice and Associate Justices of the Supreme Court of the United States.

Connie Albrecht, et al., the petitioners herein, pray that a writ of certiorari issue to review an Order entered on March 11, 1994 by the United States Court of Appeals for the Eleventh Circuit in the above entitled case. The Order denied a petition for mandamus to compel the Honorable Samuel C. Pointer, Jr., presiding judge of the United States District Court for the Northern District of Alabama, to hold a hearing on petitioners' motion to certify the

class of women who received silicone breast implants in violation of the Nuremberg Code, and failed to enter meaningful findings supporting its class certification decision.

OPINION BELOW

The order of the United States Court of Appeals for the Eleventh Circuit is printed in the Appendix, p. A-1, infra. The Order(s) of the United States District Court for the Northern District of Alabama denying class action certification are in the Appendix, pp. A-10, 11 infra. None of the opinions or orders are reported.

JURISDICTION

The jurisdiction of the United States is invoked under 28 U.S.C. § 1254 (1). The order of the United States Court of Appeals, which denied the petitioners' writ of mandamus to compel the lower court to hold a hearing on their motion to certify the class and to enter meaningful findings, was entered on March 11, 1994.

CONSTITUTIONAL PROVISIONS, RULES AND STATUTES INVOLVED

The constitutional provisions, rules and the statutes involved in this proceeding are:

U.S. Const. amend. V; Federal Rules of Civil Procedure, 23; Federal Rules of Civil Procedure, 52; Nuremberg Code.

Copies are set forth in the Appendix, p. A-2-9, infra.

STATEMENT OF THE CASE

The petitioners are 123 women who each received silicone breast implants. The defendants are implant manufacturers. The petitioners filed their class action lawsuit in the United States District Court for the District of Utah. The action is titled Albrecht, et al. v. McGhan Medical Corp, et al., Case No. 92-C-0889J (October 14, 1992). Jurisdiction was invoked under 28 U.S.C. § 1332. The lawsuit is hereinafter sometimes referred to as "the Utah class action."

Before a hearing could be held on a motion to certify the class, the Utah class action was transferred pursuant to 28 U.S.C. § 1407 with other implant litigation to the United States District Court for the Northern District of Alabama, Northern Division. The Honorable Samuel C. Pointer, Jr. presides over the transferred litigation.

The Utah class action complaint pleads a distinct cause of action not found in any other breast implant litigation: a claim for unlawful human experimentation. The legal foundation for the unique Utah claim is the Nuremberg Code. (Appendix, p. A-23-27, infra.) The Nuremberg Code war trials declared basic ethical standards for all human experimentation. See United States v. Stanley, 483 U.S. 669, 687 (1987) (J. Brennan, concurring and dissenting).

The Nuremberg Code, inter alia, explicitly provides:

> The voluntary consent of the human subject is absolutely essential. This means that the person involved . . . should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him

> to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.
>
> * * *
>
> (3) The experiment should be so designed and based on the results of animal experimentation . . . that the anticipated results will justify the performance of the experiment.

(Nuremberg Code at paragraphs 1 and 3.) The Nuremberg Code also provides:

> During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he [or she] has reached the physical or mental state where continuation of the experiment seems to him [or her] to be impossible.

(Nuremberg Code at paragraph 9.) These basic principles underlie modern tort theory and subsequent ethical pronouncements on human experimentation.

The petitioners' complaint alleges that the breast implant manufacturers did not conduct adequate animal tests or reveal then known risks to the implant recipients. (Appendix p. A-23-27, infra.) Thus, the women are ipso facto subjects of mass human experimentation in violation of the Code principles.

Under the Nuremberg Code, the women do not have to show causation or injury. Moreover, under the Nuremberg Code theory,

the petitioners seek a mandatory affirmative injunction requiring the manufacturers to inform all breast implant recipients of the known risks and side effects. Being fully informed would confer on each petitioner a meaningful opportunity to bring the experiment to an end by removal of the implants and breast reconstruction at the manufacturer's expense.

After commencing the implant litigation, Judge Pointer requested the litigants to identify pending motions. In response, the petitioners notified the Court that there was a pending motion to certify the Utah lawsuit as a class action. The petitioners requested a hearing. (Appendix, p. A-15-16 infra.) However, Judge Pointer did not hold a hearing. Instead, without notice, and in a conference with other counsel, the Court made the following bench ruling:

THE COURT: The very first one, Albrecht v. McGhan, motion for class certification 92-11104. There's an effort to certify a class for certain claims based upon battery and violations of the Nuremberg Code.

VOICE: Your Honor.

THE COURT: Before you say anything, I am going to deny the motion for class certification.

(Laughter)

Transcript of Proceedings of January 2, 1993, p. 161, lns. 17-25.[1]

---

[1] A copy of the transcript is attached in Appendix, p. A-12-14, infra.

Unaware that the Court had ruled, petitioners' counsel again requested a hearing (Appendix, p. A-17-22 infra.) Without a hearing, the Court responded with a one-sentence order denying certification. (Appendix, p. A-11, infra.)

Because of the perfunctory nature of the Order, the petitioners filed a Motion that Findings of Fact and Conclusions of Law be Entered. Again, no hearing was held, but the Court entered another order:

> Plaintiff's motion that findings of fact and conclusions of law be entered is hereby granted. The court concludes that to the extent that a class action will be utilized, the claims stated by the plaintiff on behalf of all women without bodily injuries can be dealt with most efficiently in other existing litigation rather than through a separate class action for these limited causes of action. Consequently, the motion for class certification is DENIED.

(Order entered July 12, 1993, Appendix, p. A-10, infra.)

Subsequently, the petitioners petitioned the United States Court of Appeals for the Eleventh Circuit for a writ of mandamus[2] directing Judge Pointer to vacate his order denying class certification, hold a hearing on the petitioners' motion for class certification, and enter findings of fact and conclusions of law on the subsequent certification motion. Jurisdiction was invoked under 28 U.S.C. § 1651. The petitioners said: 1) the district court, as part of its responsibility to manage class action, has a duty to hold a hearing on class action certification; 2) Rule 23

---

[2] A copy of petition is included in the Appendix, pp. A-12, infra.

requires a hearing when there is any doubt as to the proprietary of certifying the class; 3) a hearing is mandated by due process. (Petition for Writ of Mandamus p. 14, Appendix, p. A-28-49, infra.)

The petitioners also complained that the lower court failed to make any meaningful findings as required by rules 23(c) and 52(a) of the Federal Rules of Civil Procedure. (Appendix, p. A-28-49, infra.) In conclusion, the petitioners urged the Court of Appeals to apply the guidelines promulgated by the United States Court of Appeals in Bauman v. United States District Court, 557 F.2d 650 (9th Cir. 1977) and issue mandamus. On March 11, 1994, the United States Court of Appeals for the Eleventh Circuit denied the petition for mandamus.

ARGUMENT

I. WHETHER THE BASIC ETHICAL STANDARDS FOR HUMAN EXPERIMENTATION DECLARED BY THE NUREMBERG MEDICAL TRIALS IS INCLUDED WITHIN DUE PROCESS CONSTITUTIONAL LAW OR FEDERA COMMON LAW IS AN IMPORTANT QUESTION WHICH SHOULD BE DECIDED BY THIS COURT.

A. Summary of Argument.

The question of whether the Nuremberg Code is encompassed by due process or exists as federal common law is an important issue that should be resolved by this court for three reasons. First, the Nuremberg Code is a natural law document derived from "the principles of the laws of nations as they result from the usages

established among civilized people from the laws of humanity, and from the dictates of public conscience."[3] The Code's ethical standards qualify as common law. Moreover, it qualifies for review to determine whether the principles set forth in the Code are included within the due process guarantee of the fifth amendment of the U.S. Constitution. See United States v. Stanley, 483 U.S. 669, 710 (1987) (J. O'Connor concurring and dissenting). Second, the silicone breast implant litigation is unique in that it is occurring in the form of a nationwide class action. Unless the Code is declared a national ethical standard, thousands of women who have silicone breast implants but who are not yet diseased may not obtain an adequate compensation. Third, this human experimentation is pervasive, something the Nuremberg Code Panel believed must not occur in civilized societies. Thus, there is a compelling need to determine whether the Code is included within federal common law or due process.

B. Lower Court Proceedings.

The Utah class complaint alleged that the Code is the common law ethical standard for human experimentation. The petitioners moved to certify the Utah class, and requested a hearing.

The record shows that the district court's failures to hold a hearing and enter meaningful findings were due to the court's

---

3

U.S. v. Brandt, et al., Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council Law No. 10 Vol. II at 183 (1946-49).

inability to appreciate the Nuremberg Code. The district court did not treat the Nuremberg Code as the basic ethical standard for human experimentation. Instead, at a bench conference, the court rejected the claim with alacrity. See the Statement of the Case portion. The Eleventh Circuit Court of Appeals rejected petitioners' request for mandamus. In doing so, it did not rule on the issue of whether the Code is included within due process or common law.

C. Legal Analysis.

1. The Nuremberg Code.

The Nuremberg Code is a statement of ten principles found in the judgment of U.S. v. Brandt, et al.[4] Also called the "Doctor's Trial" or "Medical Case," this trial was conducted at the Palace of Justice in post-war Nuremberg, Germany. The trial covered human experimentation performed by Nazi doctors in both war-related and non-war-related activities. The judgment against the defendants concluded with a ten-point code of ethics on human

---

[4] Trials of War Criminals Before the Nuremberg Military Tribunals under Control Council Law No. 10 Vol. II at 181-82 (1946-1949). This case was one of twelve Nuremberg trials prosecuted by the United States on its own, following the War Crimes Trial which was conducted on behalf of the Allied powers. The so-called Nuremberg Principles properly refer to the London Charter, the War Crimes Trial Indictment and the judgment rendered by the Nuremberg Tribunal in the War Crimes Trial. Robert Drinan, "The Nuremberg Principles in International Law," in G. Annas & M. Grodin, eds., The Nazi Doctors and the Nuremberg Code at 174 (1992).

experimentation known as the Nuremberg Code. (Appendix, p. A-7-9, infra.)

The Code is a natural-law document derived from "the principles of the law of nations as they result from the usages established among civilized peoples, from the laws of humanity, and from the dictates of public conscience.[5] The Code's principles include: free and informed consent of the subject; adequate prior study and animal experimentation; a purpose for the good of society unobtainable by other methods; and control of the experiment by scientifically qualified persons.[6]

2. Influence of the Nuremberg Code on federal law and regulations.

The Nuremberg Code is the foundation for many U.S. statutes and regulations. In the 1950's, the National Institute of Health (NIH) adopted guidelines applicable to all healthy volunteers. In doing so, the NIH acknowledged that "the rigid safeguards observed at NIH are based on the so-called 'ten commandments'

5

U.S. v. Brandt, et al., Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council Law No. 10, Vol. 11 at 183 (1946-1949).

6

Andrew Ivy, "Nazi War Crimes of a Medical Nature," reprinted in W. Curran, Ethics in Medicine: Historical Perspectives and Contemporary Concerns, 270 (1977).

of human medical research which were adopted at the Nuremberg War Crime trials. . . ."[7]

The FDA's entry into regulation of research resulted from the Drug Amendments Act of 1962. In the wake of the thalidomide experience, when no state required physicians to inform patients that they were being given experimental drugs, the 1962 law required experts using such drugs for investigational purposes to inform patients of that fact and generally to obtain their consent.

In 1981, the Food and Drug Administration added new regulations closely modeled on Nuremberg Code principles.[8] They require an investigator who intends to use human research subjects to obtain informed consent.

Federal regulation of human experimentation also took place in other agencies. In 1974, the National Research Act created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Commission was charged with identifying basic ethical principles to govern biomedical and behavioral research involving human subjects. One year later, a comprehensive set of regulations was in place for government sponsored research with fetuses, pregnant women, and

---

[7] 49 U.S. Dept. of Health, Education and Welfare, Health Volunteers Help Scientists Conquer Disease, PHS Pub. No. 714 at 14 (1959) (NIH).

[8] 46 Fed. Reg. 8,942 (1981).

in vitro fertilization. The regulations adopted in 1975 included several of the Nuremberg Code's principles.[9]

The Code has also been considered by this Court. Four Justices discussed the Nuremberg Code in United States v. Stanley, 483 U.S. 669 (1987). The case involved LSD experiments conducted by the U.S. military on an unsuspecting army serviceman. The Court, in a split 5-4 decision, ruled that allowing Stanley to recover against the army would constitute judicial disruption of military discipline and autonomy.

The dissenting Justices said that the army's experiment violated not only Stanley's Constitutional rights, but also basic standards of human decency and civilized conduct. The dissenting opinion of Justice Brennan, in which Justices Marshall and Stevens joined, cited the importance of the Nuremberg Code.

> The medical trials at Nuremberg in 1947 deeply impressed upon the world that experimentation with unknowing human subjects is morally and legally unacceptable. The United States Military Tribunal established the Nuremberg Code as a standard against which to judge German scientists who experimented with human subjects. Its first principle was: "1. The voluntary consent of the human subject is absolutely essential."[10]

Justice Brennan further emphasized that while the military developed the Code, it also applies to civilians.

---

[9] 45 C.F.R. 46.206 (1993).

[10] 483 U.S. at 687.

Justice O'Connor, in a separate dissenting and concurring opinion stated that if the Nuremberg Code's principle requiring the subject's voluntary consent is violated, "the very least society can do is to see that the victims are compensated, as best they can be, by the perpetrators." Id. O'Connor concluded that the right to informed consent should be supported by the due process guarantee of the Constitution. Id.

3. Why the Nuremberg Code issues justify judicial review.

a. Introduction.

The Nuremberg Code purports to be a universal common law document.[11] However, in this case the district court ignored the Code. The last time this Court considered the question of whether a federal court was free to disregard common law was in Erie R. R. v. Tompkins, 304 U.S. 64, 71 (1938). The Erie court declared: "There is no federal general common law." Erie at 78. The constitutional thesis of Erie is that the federal judiciary is limited by the constitutional division of governmental power between the federal government and the states. Thus, any assertion by the federal judiciary of a general power to make law encroachs upon the power reserved to the states.

---

[11] The Nuremberg Code has been considered to be common law by at least four other courts. See Strunck v. Strunk, 445 S.W.2d 145 (Ky. Ct. App. 1969); Kamowitz v. Michigan Dept. of Mental Health, Civ. No. 73-19434-AW (Mich. Cir. Ct. 1973); Whitlock v. Duke University, 637 F. Supp. 1463 (M.D.N.C. 1986); Pierce v. Ortho Pharmaceutical Corp., 417 A.2d 505 (N.J. 1980).

However, there are at least two reasons why this court may wish to revisit and refine the Erie decision. First, Erie doesn't address what to do when litigation takes the form of a nationwide class action tort claim. In such a form, the litigation requires a nationwide common law standard, something the Nuremberg Code purports to be.

Second, the structure of government proposed by Judge Brandeise's opinion no longer exist in any recognizable form:

> Although the framers may have intended that the federal government would be a government of limited powers, in the years since Erie the Supreme Court has permitted those powers to expand so much that today the federal government has authority to regulate in virtually any area it chooses. In recent years, the only check on this expansion . . . related to state governmental operations and even this check has now been removed.

Merrill, "The Common Law Power of Federal Courts", 52 U. of Chi. L. Rev. 1, 14-15 (Winter 1985).

This petition also provides the Court with an alternative approach. The Court could decline to revisit Erie but declare that the Nuremberg Code is included within and supported by due process, as suggested in Justice O'Connor's concurring and dissenting opinion in United States v. Stanley.

As hereinafter set forth, the silicone breast implant litigation and this country's history of unconscionable human experimentation cry out for review and determination of whether the Nuremberg Code principles are included within our common or constitutional law.

b. The breast implant litigation.

At present, thousands of women have joined as plaintiffs in the multidistrict silicone breast implant litigation. In addition, as set forth in the statement of the case portion of this petition, there is a certified nationwide class action of implant recipients.[12] There is another nationwide class certified for settlement purposes only. Heidi Lindsay et al. v. Dow Corning Corp., et al. Case No. CV-94P-11558-S (U.S.D.C. N.D. of Ala., Honorable Samuel C. Pointer, Jr., presiding). However, only the Utah class action complaint pleads a violation of the Nuremberg Code. The allegations focus on the deficient experimental foundation upon which the implants were mass marketed.

Silicone breast implant recipients should have been protected by the FDA, but they were not. Implants are among the 140 categories of medical devices which manufacturers were supposed to establish as safe under the Medical Device Amendments of 1976.[13] However, in 1978 the FDA chose to rely on the assurances of financially interested plastic surgeons rather than doing its

---

[12] Donna Dante, et al. v. Dow Corning, et al., Case No. C-92-057 (U.S.D.C. N.D. of Ala., Honorable Sam C. Pointer, Jr., presiding).

[13] See 21 U.S.C. § 360(c) (1992) (providing that manufacturers of high risk devices introduced before 1976, including breast implants, must prove the safety of the devices prior to continued marketing).

own safety study.[14] The FDA finally requested test data and held public hearings on silicone gel implants in 1991. Serious safety questions were raised decades earlier.[15]

Not only were silicone breast implant recipients not protected by the FDA, they are not all adequately protected in the multi-district implant litigation. Judge Pointer's summary conclusion that the Nuremberg Code claims could be more efficiently handled in existing litigation is incorrect. Because the Nuremberg Code does not require proof of causation or injury, the Code is tailor-made to protect women who are not yet diseased. However, women without disease may not be adequately compensated. A proposed class implant settlement calls for five funds totalling $4.3 billion. (Appendix, p. A-50-64, infra.) However, women who are not diseased and who do not have implant ruptures, are given

---

[14]

68 Chi.-Kent. L. Rev. 409, 418. The FDA's complaisance was at least partially the result of insufficient manpower and funding to accomplish the ambitious objectives set out by Congress in the Medical Device Amendments to the Food, Drug and Cosmetic Act.

> . . . in 1976, the FDA's device bureau employed [only] 132 people, including secretaries and file clerks, to review more than 1,700 types of devices. . . . By comparison, 1013 employees were working on ongoing drug review. . . . In 1990, the combined device and radiological center had 860 employees, while the drug center had 1223 employees.

Miolleson, "Consumer Concerns Put Focus on FDA Safety Reviews," Chicago Trib. § 1 at 8 (Jan. 26, 1992).

[15]

See Ingersoll, "Amid Lax Regulation, Medical Devices Flood a Vulnerable Market," Wall Street J. at A6 (March 24, 1992).

access to only two of the compensation funds: the explantation fund and the compensation fund. Each fund will have approximately $722,000,000 ($4.3 billion x. 16.8%). However, since there may be over a million women with implants but no rupture or disease, the compensation contemplated by the agreement could amount to only about $1,444 per person.

If, however, the Nuremberg Code is declared part of the federal common law or due process constitutional law, the women will be armed with a powerful legal theory they can use to secure adequate compensation. They can also obtain an injunction requiring removal to end the experiment.

The Nuremberg Code so provides:

> During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he [or she] has reached the physical or mental state where continuation of the experiment seems to him [or her] to be impossible.

(Nuremberg Code at paragraph 9.)

D. Other Human Experimentation.

The Nuremberg Judicial Panel assumed that the Code's principles were basic ethical standards accepted by all civilized societies. However, the recent information and pending release of millions of documents concerning U.S. radiation testing on human subjects

casts doubt on the panel's assumption.[16] The extent of U.S. government involvement in human experiments is considerable:

> In 1977, it was revealed that the CIA, in conjunction with the military, had for 25 years carried out mind control experimentation on unwitting U.S. and Canadian research subjects. . . . Involved were 185 non-government researchers at 80 institutions. . . .
>
> The experimentations ranged from chemical and biological warfare to hypnosis, use of strange pathogens or other toxin agents, and electro-sleep, all designed to elicit secret thoughts. At the hearings conducted by Senators Inouye and Kennedy in 1977, Admiral Stansfield Turner, then CIA director, agreed to set into motion a process which would uncover those unwitting victims and assess damage. This was never done.
>
> From 1980 to 1988, nine Canadians fought a court battle to sue the CIA for funding experiments carried out at McGill University in Montreal in the Allan Memorial Institute, a psychiatric hospital. The experiments, designed to develop brainwashing procedures, had effectively destroyed these victims' lives. . . .
>
> There is more. During the 1950s and '60s, 8000 U.S. servicemen participated in chemical and biological warfare experimentation; 1,000 of these were unwitting recipients of LSD, many others of BZ, a more powerful hallucinogenic drug. The films of men being experi-

---

16

On January 25, 1993, the government acknowledged that radiation experiments are still continuing. Secretary O'Leary of the Department of Energy stated before a Senate hearing that she believes all subjects have given informed consent to the procedures, but that victims should be compensated for damages. Some Senate members expressed concern that "rogue researchers" may be conducting experiments without the ethical required consent.

> mented upon are a chilling testament to a callous disregard for human life. . . .
>
> During this century, there have been other examples of the medical profession's collaboration with government agencies in unethical experimentation. Included is the Tuskegee experiment of the Public Health System where 400 poor, black men were denied treatment for syphilis for 40 years so that the natural course of the disease could be followed.[17]

The foregoing examples demonstrate there is a compelling need to determine whether the Nuremberg Code principles are included within the concept of due process or federal common law.

II. CERTIORARI SHOULD BE GRANTED TO RESOLVE THE IMPORTANT ISSUE OF WHEN A UNITED STATES DISTRICT COURT MUST PROVIDE NOTICE AND AN OPPORTUNITY TO BE HEARD PRIOR TO DENYING A MOTION TO CERTIFY THE CLASS.

A. Summary of Argument.

In General Telephone Co. of Southwest v. Falcon, 457 U.S. 147 (1982) the Court criticized the practice of certifying class actions absent a hearing unless it is apparent from the pleadings whether Rule 23 requirements are met. In Eisen v. Carlisle, 417 U.S. 156 (1974), the Court ruled that the district court should not hold a mini-trial on the merits. What remains to be decided is whether due process or F.R.C.P. 23 requires a hearing on the Rule 23 elements in contested class certification proceedings. Since the

---

[17] H. Weinstein, "Test Disclosures Show 'Misguided Patriotism,'" San Francisco Chronicle (Jan. 21, 1994) at A23.

issue concerns the construction and application of the Federal Rules of Civil Procedure, which it is the duty of this Court to formulate and put in force, the issue is appropriate for certiorari. See Schlagenhauf v. Holder, 379 U.S. 104, 112 (1964). The importance of the question in the administration of civil justice together with existing uncertainty also warrants certiorari. La Buy v. Howes Leather Co., 352 U.S. 249 (1957).

B. Proceedings in the Lower Court.

As set forth in the statement of the case section, the petitioners twice requested a hearing and twice the district court declined to hold one.

The petitioners filed a petition for mandamus with the United States Court of Appeals for the Eleventh Circuit. (Appendix, p. A-28-49, infra.) In the petition, the Utah plaintiffs said that the district court had a mandamus duty to hold a hearing on the motion to certify the class. They explained that the duty springs from: 1) due process; 2) Rule 23; and 3) the court's duty to conduct, and manage complex class litigation. See Morrison v. Booth, 730 F.2d 642 (11th Cir. 1984).

The Eleventh Circuit Court of Appeals denied mandamus.

C. Legal Analysis.

1. Due process.

At least one Circuit Court of Appeals have ruled that due process requires notice and an opportunity to be heard in contested class certification proceedings. See In re Temple, 851 F.2d 1269, 1272 (11th Cir. 1988).

2. Rule 23.

Rule 23 of the Federal Rules of Civil Procedure requires the petitioners to satisfy the well known touchstones of numerosity, commonality, typicality and adequate representation. In addition, the petitioners must satisfy at least one of the elements of Rule 23(b). These issues, for the most part, are factual issues -- see Sirota v. Solitron Devices, Inc., 673 F.2d 566, 571 (2d Cir. 1982) (numerosity, typicality, commonality) -- or are at least emeshed in factual and legal issues. See e.g., General Telephone Co. of Southwest v. Falcon, 457 U.S. 147, 160 (1982).

In those rare cases where it is obvious that Rule 23 requirements exist, the district court may so rule based on the complaint. E.g., General Telephone, supra; Bradford v. Sears, Roebuck and Co., 673 F.2d 792, 795-96 (5th Cir. 1982). However, if there is any doubt as to the propriety of a class action, the district court is required to conduct an evidentiary hearing. E.g., Morrison, supra at 643-44; Bradford, supra at 796.

3. Duty to manage the class action litigation.

The district court has the responsibility, independent of the litigants, to conduct and manage complex class action litigation. Morrison v. Booth, 730 F.2d 642, 644 (11th Cir. 1984); Ezell v. Mobile Housing Board, 709 F.2d 1376, 1380 (11th Cir. 1983). This responsibility includes the duty to hold an evidentiary hearing on the propriety of the litigation proceeding as a class action. Morrison, supra at 643-644; See Ezell, supra at 1380.

III. THE RELATED ISSUES OF WHETHER MANDAMUS MAY BE USED TO REVIEW AND CORRECT CLASS ACTION CERTIFICATION PROCEEDINGS AND, IF SO, UNDER WHAT CIRCUMSTANCES, ARE IMPORTANT QUESTIONS OF FEDERAL LAW WHICH SHOULD BE DECIDED BY THIS COURT.

A. Summary of Argument.

Whether mandamus may be used to review and correct an order denying class action certification is an issue unresolved by this Court. The Sixth, Ninth, Tenth and Eleventh Circuit Court of Appeals have all ruled that mandamus is an appropriate procedural remedy.

This case presents the opportunity to determine whether orders granting or denying class status may be reviewed by mandamus and, along with it, an opportunity to establish uniform criteria for mandamus review.

B. Proceeding Before the Lower Court.

This case has proceeded in a manner comparable to that described in Schlagenhauf v. Holder, 379 U.S. 104, 106-109 (1964). Petitioners moved for class certification and requested a hearing. When a decision was made without a hearing, petitioners sought mandamus to compel a hearing. Since mandamus was denied, petitioners seek certiorari.

C. Legal Analysis.

Orders denying or granting class action certification are not final orders. General Telephone Co., supra. They are not reviewable under 28 U.S.C. § 1291. E.g., Bradford v. Sears,

Roebuck & Co., 673 F.2d 792, 793-94 (5th Cir. 1982). The issue presented in this petition is whether such orders are reviewable via mandamus under the all writs statute (28 U.S.C. § 1651), and if so under what criteria.

Mandamus is traditionally issued by federal courts "to confine an inferior court to a lawful exercise of its prescribed jurisdiction as to compel it to exercise its authority when it is its duty to do so." Roche v. Evaporated Milk Ass'n, 319 U.S. 21, 26 (1943).

The federal courts never confined themselves to a strict definition of jurisdiction, but it is clear that only exceptional circumstances justify mandamus. Will v. United States, 389 U.S. 90, 95 (1967). Schlagenhauf v. Holder, 379 U.S. 109, 110 (1964). Specifically, the writ is invoked when a district court judge displays a persistent disregard of the Rules of Civil Procedure promulgated by this Court. E.g., La Buy v. Howes Leather Co., 352 U.S. 249 (1957).

This Court has not ruled whether mandamus will issue to review and correct defective class certification proceedings, several Circuit Courts of Appeals have declared that mandamus is an appropriate procedural remedy.

In Bauman v. United States Dist. Court, 557 F.2d 650 (9th Cir. 1977), the Court of Appeals for the Ninth Circuit developed five guidelines or factors to determine whether a class action certification proceeding will be corrected by issuing a writ of mandamus. First, the party seeking the writ must lack other adequate means, such as a right of direct appeal, to obtain the

desired relief. The second related factor is whether the petitioners will be damaged or prejudiced in a way not correctable on appeal. The third guideline is whether the district court's order is clearly erroneous. The fourth factor is whether an oft-repeated error occurred or whether the district court manifested a disregard of the federal rules. The fifth factor is whether the certification order raises new and important problems or issues of first impression. Id. at 652-653.[18]

The Ninth Circuit's five guidelines are accepted by the Courts of Appeal for the Sixth and Tenth Circuits. See In re Bendectin Products Liability Litigation, 749 F.2d 300 (6th Cir. 1984); In re Dalton, 733 F.2d 710, 716-717 (10th Cir. 1984). The Eleventh Circuit Court of Appeals adopted a similar analytical framework in In re Temple, 851 F.2d 1269, 1270-71 (11th Cir. 1988), and ordered a hearing on a motion to certify the class.

Since all of the five factors enunciated in Bauman are present in this case, this petition presents an excellent opportunity to define the law of mandamus as it applies to class certification proceedings. Because of the wide implication for the administration of civil justice this issue qualifies for certiorari. See Will v. United States, 359 U.S. 90 (1967).

---

[18] Three of the five factors are based on Supreme Court precedent. The first factor is derived from Kerr v. United States District Court, 426 U.S. 394, 403 (1976). The fourth factor comes from La Buy v. Howes Leather Co., 352 U.S. 249, 255-60 (1957). The fifth factor is based on Schlagenhauf v. Holder, 379 U.S. 104, 111 (1964).

IV. WHETHER A DISTRICT COURT HAS A DUTY TO MAKE MEANINGFUL FINDINGS IN SUPPORT OF AN ORDER DENYING CLASS CERTIFICATION IS AN IMPORTANT ISSUE WARRANTING CERTIORARI.

A. Summary of Argument.

F.R.C.P. 52(a) requires a trial judge to make findings of fact and conclusions of law in all civil actions tried upon the facts without a jury. The rule is mandatory and must be reasonably complied with. E.g., Commissioner v. Duberstein, 363 U.S. 278, 292 (1959). This case presents the issue of whether F.R.C.P. 52 (a) applies to orders granting or denying class certification.

B. Lower Court Proceedings.

In response to the petitioners' motion to enter findings of fact and conclusions of law, the district court made a one-paragraph order set forth in the Statement of the Case portion.

However, the Court's sole conclusion is of no consequence. Apparently that lone finding relates to Rule 23(b)(3). It doesn't matter whether the petitioners made the showing required by Rule 23(b)(3) because they clearly met the requirements of Rule 23(b)(2). Hence, the district court made no meaningful findings.

C. Legal Analysis.

When a district court judge rules upon such factual issues, F.R.C.P. 52(a) requires the district court to "find the facts specially and state separately its conclusions of law thereon." The Rule 52 duty to make findings applies to certification proceedings. The district court must make findings on each essential element

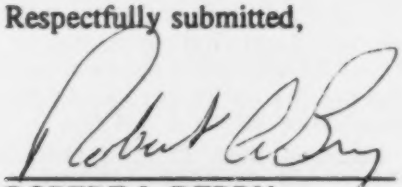
specified in Rule 23. E.g., Bradford v. Sears, Roebuck and Co., 673 F.2d 792 (5th Cir. 1982); Price v. Lucky Stores, Inc., 501 F.2d 1177, 1179 (9th Cir. 1974).

CONCLUSION

The issues raised in this petition desmonstrate special and important reasons for granting certiorari. The issue of whether the Nuremberg Code is included within due process constitutional law or federal common law is an important and basic question of federal law which has not been, but should be, settled by this Court. The other three unresolved issues warrant certiorari because they concern the Federal Rules of Civil Procedure, which it is the duty of this Court to enforce and define.

For these reasons, certiorari to the United States Court of Appeals for the Eleventh Circuit should be granted.

Respectfully submitted,



ROBERT J. DEBRY
Robert J. DeBry & Associates
4252 South 700 East
Salt Lake City, UT 84107
(801) 262-8915
Counsel for Petitioners

Dated this 9th day of June, 1994.

No.

IN THE
SUPREME COURT OF THE UNITED STATES

October Term, 1994

CONNIE ALBRECHT, et al.,

Petitioners,

v.

UNITED STATES DISTRICT COURT JUDGE
FOR THE NORTHERN DISTRICT OF ALABAMA
HONORABLE SAMUEL C. POINTER, JR., PRESIDING
AND McGHAN MEDICAL CORPORATION, et al.,

Respondents.

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

APPENDIX TO PETITION FOR WRIT OF CERTIORARI

ROBERT J. DEBRY
Counsel of Record
ROBERT J. DEBRY & ASSOCIATES
4252 South 700 East
Salt Lake City, UT 84107
(801) 262-8915
Counsel for Petitioners

TABLE OF CONTENTS

ORDER DENYING MANDAMUS A-1

CONSTITUTIONAL PROVISIONS,
RULES AND STATUTES . . . . . A-2 - A-9

DISTRICT COURT ORDERS . . . . . A-10 - A-11

TRANSCRIPT OF DISTRICT
COURT PROCEEDINGS . . . . . A-12 - A-14

LETTERS TO THE DISTRICT
COURT REQUESTING A HEARING . . . . A-15 - A-22

PORTION OF THE COMPLAINT
PLEADING THE NUREMBERG CODE . . A-23 - A27

PETITION FOR WRIT OF MANDAMUS . A-28 - A-49

PORTIONS OF THE PROPOSED
NATIONWIDE CLASS ACTION
SETTLEMENT AGREEMENT . . . . . A-50 - A-64

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 94-6130

IN RE:

CONNIE ALBRECHT,
CLAUDIA ARCHULETA,
LYNN ATHERLEY,
MARY JANE BALOK,
SAYY BARELA, et al.,

Petitioners,

- - - - - - - - - -

On Appeal from the United States District Court for the Northern District of Alabama

- - - - - - - - - -

BEFORE: HATCHETT, DUBINA and CARNES, Circuit Judges.

BY THE COURT:

Petitioners' petition for writ of mandamus is denied.

AMENDMENTS TO THE CONSTITUTION

AMENDMENT 5

No person shall be held to answer for a capital, or otherwise infamous crime, unless on a presentment or indictment of a Grand Jury, except in cases arising in the land or naval forces, or in the Militia, when in actual service in time of War or public danger; nor shall any person be subject for the same offence to be twice put in jeopardy of life or limb; nor shall be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation.

FEDERAL RULES OF CIVIL PROCEDURE

Rule 52. **Findings by the Court; Judgment on Partial Findings**

(a) **Effect.** In all actions tried upon the facts without a jury or with an advisory jury, the court shall find the facts specially and state separately its conclusions of law thereon, and judgment shall be entered pursuant to Rule 58; and in granting or refusing interlocutory injunctions the court shall similarly set forth the findings of fact and conclusions of law which constitute the grounds of its action. Requests for findings are not necessary for purposes of review. Findings of fact, whether based on oral or documentary evidence, shall not be set aside unless clearly erroneous, and due regard shall be given to the opportunity of the trial court to judge of the credibility of the witnesses. The findings of a master, to the extent that the court adopts them, shall be considered as the findings of the court. It will be sufficient if the findings of fact and conclusions of law are stated orally and recorded in open court following the close of the evidence or appear in an opinion or memorandum of decision filed by the court. Findings of fact and conclusions of law are unnecessary on decisions of motions under Rule 12 or 56 or any other motion except as provided in subdivision (c) of this rule.

(b) **Amendment.** Upon motion of a party made not later than 10 days after entry of judgment the court may amend its findings or make additional findings and may amend the judgment accordingly. The motion may be made with a motion for a new trial pursuant to Rule 59. When findings of fact are made in actions tried by the

court without a jury, the question of the sufficiency of the evidence to support the findings may thereafter be raised whether or not the party raising the question has made in the district court an objection to such findings or has made a motion to amend them or a motion for judgment.

(c) **Judgment on Partial Findings**. If during a trial without a jury a party has been fully heard with respect to an issue and the court finds against the party on that issue, the court may enter judgment as a matter of law against that party on any claim, counterclaim, cross-claim or third-party claim that cannot under the controlling law be maintained or defeated without a favorable finding on that issue, or the court may decline to render any judgment until the close of all the evidence. Such a judgment shall be supported by findings of fact and conclusions of law as required by subdivision (a) of this rule.

Proposed Amendment: Subject to Congressional disapproval, the proposed amendment to Rule 52 becomes effective December 1, 1993. The proposed amended Rule 52 provides:

"Rule 52. Findings by the Court; Judgment on Partial Findings

"(a), (b) [Unchanged]

"(c) **Judgment on Partial Findings**. If during a trial without a jury a party has been fully heard on an issue and the court finds against the party on that issue, the court may enter judgment as a matter of law against that party with respect to a claim or defense that cannot under the controlling law be maintained or defeated to

render any judgment until the close of all the evidence. such a judgment shall be supported by findings of fact and conclusions of law as required by subdivision (a) of this rule."

Notes of Advisory Committee on September 22, 1992 proposed amendment to Rule. This technical amendment corrects an ambiguity in the text of the 1991 revision of the rule, similar to the revision being made to Rule 50. This amendment makes clear that judgments as a matter of law in nonjury trials may be entered against both plaintiffs and defendants and with respect to issues or defenses that may not be wholly dispositive of a claim or defense.

FEDERAL RULES OF CIVIL PROCEDURE

Rule 23. **Trial by Jury or by the Court**

(a) **Trial by Jury**. Cases required to be tried by jury shall be so tried unless the defendant waives a jury trial in writing with the approval of the court and the consent of the government.

(b) **Jury of less than twelve**. Juries shall be of 12 but at any time before verdict the parties may stipulate in writing with the approval of the court that the jury shall consist of any number less than 12 or that a valid verdict may be returned by a jury of less than 12 should the court find it necessary to excuse one or more jurors for any just cause after trial commences. Even absent such stipulation, if the court finds it necessary to excuse a juror for just cause after the jury has retired to consider its verdict, in the discretion of the court a valid verdict may be returned by the remaining 11 jurors.

(c) **Trial without a jury**. In a case tired without a jury the court shall make a general finding and shall in addition, on request made before the general finding, find the facts specially. Such findings may be oral. If an opinion or memorandum of decision is filed, it will be sufficient if the findings of fact appear therein.

THE NUREMBERG CODE OF ETHICS IN MEDICAL RESEARCH

(1) The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent: should be so situated as to be able to exercise free power of choice without the intervention of any element of force, fraud, deceit, duress, over reaching, or other ulterior form of constraint or coercion and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

(2) The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

(3) The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural

history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.

(4) The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

(5) No experiment should be so conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps in those experiments where the experimental physicians also serve as subject.

(6) The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

(7) Proper preparations should be made and adequate facility provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

(8) The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

(9) During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

(10) During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill, and careful judgment required of him, that a

continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF ALABAMA

ALBRECHT, Plaintiff(s);	)	
vs.	)	No. CV92-P-11104-S
MCGHAN MEDICAL, Defendant(s).	)	

ORDER

Plaintiff's motion that findings of fact and conclusions of law be entered is hereby GRANTED. The court CONCLUDES that to the extent that a class action will be utilized, the claims stated by the plaintiff on behalf of all women without bodily injuries can be dealt with most efficiently in other existing litigation rather than through a separate class action for these limited causes of action. Consequently, the motion for class certification is DENIED.

Dated: July 12, 1993.

CHIEF JUDGE SAM C. POINTER, JR.

Service List:
Robert J. DeBry

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA

ALBRECHT, Plaintiff(s);	)	
vs.	)	No. CV92-P-11104-S
MCGHAN MEDICAL, Defendant(s).	)	

ORDER

Plaintiff's motion for class certification is hereby DENIED.

Dated: May 25, 1993

CHIEF JUDGE SAM C. POINTER, JR.

Service List:
Robert J. Debry

OFFICIAL TRANSCRIPT
BEFORE THE

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
Southern Division

In Re:

SILICONE GEL BREAST

IMPLANT PRODUCTS LIABILITY Master File No.

LITIGATION (MDL 926) CV-92-P-10,000-S

Washington, D.C.
Friday, January 22, 1993

HEARING

ALDERSON REPORTING COMPANY, INC.
1111 FOURTEENTH STREET N.W.
SUITE 400
WASHINGTON, D.C. 20005
(202) 289-2260

liability issue. And I death with two cases from South Carolina.

MS. TROUTWINE: Shearman.

THE COURT: Shearman.

MS. TROUTWINE: You told us you were going to do Shearman but you haven't.

THE COURT: No, I have done Shearman.

VOICE: You continued it.

THE COURT: What I did with Shearman was to say that I needed more information and further discovery about whether Recticell does any -- has any principal place of business or note. That was that particular issue.

Those are the only ones that I came prepared to deal with. It is very difficult, as you can imagine, to keep up with the cases in which there is some -- no, I'm sorry, there's one additional one.

The very first one, Albrecht v. McGahn, motion for class certification in 92-11104. There's no effort to certify a class for certain claims based upon battery and violations of the Nuremberg Code.

VOICE: Your Honor --

THE COURT: Before you say anything, I'm going to deny the motion for class certification.

(Laughter)

THE COURT: To the extent that these are

appropriate claims and to the extent we're going to have a class; I can deal with it in other litigation without the need to utilize this particular device for certain limited theories of action. that is in no way a ruling on the merits of whether any such claims could be presented individually or as a class theory.

MR. WOODSIDE: I would like to report to the Court, now that you have ruled that way, you are consistent with several State courts in Utah which have ruled similarly in similar actions by Mr. DuVries.

THE COURT: I wonder if there's been any inadequate opportunity for plaintiffs' counsel and Baxter to discuss matters about the attorneys fee, the quantum of attorneys fees and expenses? Can we deal with it separately? Or whichever way you want to do it.

MR. KNOWLES: Judge, let me report, we did talk by the problem is, as you recognized even not knowing it, we spent almost no time worrying about the -- this is not to say we want to waive it, but worrying about the issue of calculating our fees and expenses.

I have some rough numbers on that, but I think that probably the more appropriate way to do it would be within the next few days, to send to Debra, and then if she can have a few days to object if she wants. Although Debra said she wanted us to provide affidavits and

October 30, 1992

Honorable Sam C. Pointer, Jr.
United States District Judge
U.S. District Court
Federal Courthouse
Birmingham, AL 35203

In Re: Silicone Gel Breast Implants Products Litigation (MDL-926)

Listing of Motions Which Merit Early Attention

Master File No. CV92-P-10000-S

Honorable Sir:

On October 6, 1992, your clerk, Jonathan Banks, wrote to all parties in MDL 926 requesting a list of motions which merit early attention. Pursuant to that request, we suggest that the following motion merits early attention.

Case Name:	Albrecht et al. v. McGhan Medical Corp. et al.
Case Number: (originating unit)	92-C-0089J
Name of Motion:	Motion for Class Certification Respecting Counts XII, XIII, AND XIV. (Defendant Dow Corning only.)
Suggested Briefing Schedule:	Plaintiffs' motion and supporting memorandum has been filed. Plaintiffs suggest that defendant Dow Corning have 30 days to file an opposing memorandum, and that plaintiffs have 15 days to file a reply memorandum. A hearing could be scheduled for December or early January.
Reasons That This Motion Merit Early Attention:	A class action has already been certified in the case of Dante v. Dow Corning by Judge Rubin. That existing class action has

been transferred to the Northern District of Alabama pursuant to MDL Order 926. This case (Albrecht) seeks certification for claims and theories not presently included in the Dante case. (viz. battery and violations of the Nuremberg Code.) If granted, this pending motion would have enormous impact on every aspect of the consolidated cases. All pending issues of discovery, trial preparation, notice, etc., would be affected by the Albrecht case

We attach for the Court's consideration a copy of the Complaint, the Motion For Class Certification Respecting Counts XII, XIII, and XIV, plus the supporting memorandum.

Finally, in Order No. 1, this Court requested counsel to submit "preliminary reports" to familiarize the Court with each case (or group of cases). Of course, this case had not yet been filed when Order No. 1 was signed (June 26); Therefore, there was no "preliminary report" to acquaint the Court with this case. Therefore, this letter, with attachments, would serve the dual role of identifying motions for early consideration, plus a "preliminary report" to acquaint the Court with this case. Thank you for your consideration in this matter.

Sincerely,

ROBERT J. DEBRY & ASSOCIATES

Robert J. DeBry

RJD/sc
Attachments

cc: Plaintiffs' Liaison Counsel
Defendants' Liaison Counsel

June 7, 1994

Honorable Sam C. Pointer, Jr.
U.S. District Court
Northern District of Alabama
U.S. Courthouse
Birmingham, AL 35203

RE: Urgent Request to Set Hearing Date in the Case of Albrecht v. McGhan Medical, et al. (92-P-11104-S)

Dear Judge Pointer:

On October 29, 1992, plaintiffs filed a Motion for Class Certification in this case. (See Exhibit A.) No hearing date has been set. Recent events suggest an urgent need to set a hearing date on this pending motion.

OVERVIEW OF PENDING MOTION

As the Court is aware, a class has already been certified in the case of Donna Dante v. Dow Corning, et al.,. (hereafter the "Dante class").

The pending motion in this case (Albrecht) (hereafter the "Albrecht class") seeks to certify a class with respect to three special issues which do not fall under the existing Dante class. Specifically, Albrecht sets up claims for continuing common law battery, for unlawful human experimentation in violation of principles of the Nuremberg Code[1]; and for violations of the Magnusson-Moss Warranty Act.

---

1 United States v. Karl Brandt, Trials of War Criminals Before the Nuremberg War Tribunal, Vol. I and II. The Medical Case. Washington, D.C., U.S. Government Printing Office. (1948).

Rule 23(c)(4)(A) specifically authorizes the creation of such classes for special issues:

> An action may be brought or maintained as a class action with respect to particular issues.

See Also Manual on Complex Litigation, Second § 30.17.

DISTINCTIVE ASPECTS OF THE PROPOSED ALBRECHT CASE

The proposed Albrecht class adds three important concepts to this consolidated litigation.

First, in order to win a case for violations of the Nuremberg Code, it is not necessary to show causation. That is, it is not necessary to show that the breast implant caused some physical injury. Rather it is only necessary to show that informed consent was lacking or defective. The remedy for violations of the Nuremberg Code is to give women the option to "bring the experiment to an end." (See Nuremberg Code at para. 9.) Or, stated in other words, to give women an option to have the breast implants removed.

Second, the theory of battery is in reality a claim for "continuing battery." That is, the unconsented touching continues so long as the breast implant remains in the woman's body. Note that (as in the case of Nuremberg Code violations) it is not necessary to prove causation to win a claim for common law battery. Rather it is only necessary to prove an unconsented touching.[2] The remedy for such an unconsented touching is simply to end the continuing battery. Or stated in other words, to give women the option to have the breast implants removed.

Third, because the unconsented touching continues, statutes of limitations have not yet begun to run.

---

2 Of course if the unconsented touching causes physical injury, an additional element of damages is present.

RELATIONSHIP OF LEGAL THEORIES IN ALBRECHT CLASS AND THE DANTE CLASS

The Dante class pleads claims for bodily injury caused by the breast implants. The complaint also pleads a "medical monitoring fund." However that fund is to compensate women who "are likely to suffer" some future bodily injury.[3]

In contrast, the Albrecht class includes claims for women who simply want to have the breast implants removed (or the financial equivalent of removal).[4] In effect, the Albrecht class would operate as a sort of nationwide recall of the defective breast implants for women who can and do allege injuries in excess of $50,000.

A simple analogy might be an automobile with a defective part. Traditional tort theories would recover for personal injuries caused after the defective part causes a crash. However, society

---

[3] The order certifying Dante describes the class as: "a) Such persons who as a result of the silicone gel breast implant have sustained any adverse medical condition thereby; and b) those persons who are likely to suffer or are at an increased risk of suffering any adverse medical condition as a result of having received a silicone gel breast implant, and who may be in need of medical monitoring to facilitate early detection of any such future condition." (See Exhibit B and C.)

[4] point of fact, the Albrecht complaint covers claims for women who can in good faith allege injuries in excess of $50,000. There is pending in Utah state court a Jane Doe nationwide class action, not yet certified, which pleads for rescissory damages for less than $50,000 for women who have not previously made a claim in a legal action against Dow Corning for tortious bodily injuries and who simply seek compensation sufficient to cover the costs of their original implants and expenses in again consulting a physician or surgeon, hospital costs, and other actual medical expenses involved.

is ill served if people must continue to drive the defective cars (or to bear the defective breast implant) until an injury occurs. Society is better served by a nationwide recall to replace or repair the faulty part (or breast implant) before injury occurs.

Although admittedly an oversimplification, the Dante class might be seen to encompass 1% of all women who have ever had breast implants. (viz. those women who can prove a bodily injury or who are "likely" to suffer a future bodily injury.) However, 100% of the women who have ever received breast implants may be entitled to damages under theories of common law battery, violations of the Nuremberg Code, and violations of the Magnusson-Moss Warranty Act. (viz. a nationwide recall of a defective product.)

Finally, it is entirely possible that the Dante class may lose at trial because they cannot meet the burden of causation; while at the same trial, the proposed Albrecht class may win because causation is not an issue for common law battery, or for violations of the Nuremberg Code, or for violations of the Magnusson-Moss Warranty Act.

GENERAL STANDARDS FOR EARLY RULING

Rule 23(c)(1) provides that class certification shall be determined "as soon as practicable." (See also Manual on Complex Litigation, Second, § 30.11.) However, the issue here is more fundamental. The issue is simply getting the matter on the Court's calendar. Rule 78, Federal Rules of Civil Procedure provides:

> Unless local conditions make it impracticable, each district court shall establish regular times and places, at intervals sufficiently frequent for the prompt dispatch of business, at which motions requiring notice and hearing may be heard and disposed of. . . .

This Court certainly has great latitude in administering that rule. However, the spirit of the rule contemplates that matters will not be held in abeyance for any extended time. The Manual on Complex Litigation, Second provides similar guidance at § 21.32:

> . . . potentially meritorious motions -- particularly those which, if granted, would substantially affect further proceedings in the litigation -- should be welcomed by the Court and given prompt attention. (Emphasis added.)

NEED FOR URGENT ACTION

This letter to the Court is triggered by a Breast Implant Bulletin which has recently been circulated. (See Exhibit D.) The Bulletin describes "secret negotiations" which may be underway to settle the pending class action. Presumably those settlement negotiations would settle the Dante claims.

However, the Dante class can only negotiate to settle claims distinctive to that action. That is to say, the Dante class cannot, somehow, negotiate for a global settlement to include claims (such as continuing battery or violations of the Nuremberg Code) not included in the Dante complaint and other unique classes of claimants.

> Occasionally the parties propose a settlement covering a class different from that certified. Typically, the parties propose to enlarge the class--or the claims of the class --to give the settling defendants greater protection against further litigation. . . . The problem presented by these requests is not the lack of sufficient information and scrutiny, but rather the possibility that fiduciary responsibilities of class counsel or class representatives may have been compromised.

Manual on Complex Litigation, Second, § 30.45.

Therefore, any settlement of the Dante claims would, of necessity, be a partial settlement. Claims in the Albrecht class and in the Jane Doe nationwide Utah state class would remain to be litigated another day. However, the Manual gives special warning about the problems of a partial settlement (See Manual on Complex Litigation, Second at § 30.46). Steps should be taken that this in reality will not be just a partial settlement depleting available funds. (See Manual on Complex Litigation, Second, at §§ 30.212 and 30.44.) Moreover, substantial confusion would certainly arise if women were to receive notice of a settlement in Dante (for

injuries) before they are ever aware that they may have rights even though they may not have suffered any bodily injury (viz. the Albrecht class).

In summary, this Court should urgently hold hearings regarding any sub-classes or special classes. Only after the metes and bounds of the class are known, can settlement discussions be fairly conducted for the benefit of all women who have received the defective breast implants.

Sincerely,

ROBERT J. DEBRY

RJD/vah
Attachments

cc: Plaintiff's Liason Counsel
Defendant's Liason Counsel

IN THE FEDERAL DISTRICT COURT
FOR THE DISTRICT OF UTAH, CENTRAL DIVISION

CONNIE ALBRECHT, individually, Plaintiff, vs. McGHAN MEDICAL CORP. INAMED CORP., HEYER-SCHULTE CORP., AM HOSPITAL SUPPLY CORP., BAXTER HEALTH-CARE CORP., BAXTER INC., MENTOR CORP., and DOW CORNING CORP. CORPORATION, Defendants.	**SECOND AMENDED COMPLAINT (CLASS ACTION[1]) (JURY TRIAL DEMANDED)** Case No. 92-C-0889J Alabama Case No. 92-P-11107-S Judge Bruce S. Jenkins MDL Judge Sam C. Pointer

1

Counts I-XI are pleaded as individual claims. Counts XII, XIII and XIV are pleaded as a class action. See, Rule 23(c)(4)(A) F.R.C.P.

COUNT XIII

UNLAWFUL HUMAN EXPERIMENTATION

82. Plaintiffs reallege each and every paragraph and allegation above as if fully set forth herein.

83. The Nuremberg Code[2] is a part of international law ratified by the United Nations General Assembly and to which the United States is a consenting party; it effectively sets a minimum standard of care by governments and institutions and individuals therein with regard to experimentation on human beings.

84. The Nuremberg Code inter alia provides that:

> The voluntary consent of the human subject is essential. This means that the person involved . . . should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.
>
> * * *
>
> The experiment should be so designed and based upon the results of animal experimentation... that the anticipated results will justify the performance of the experiment.

[2] United States v. Karl Brandt, Trials of War Criminals Before the Nuremberg War Tribunal, Vol. I & II, The Medical Case.

* * *

> The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

* * *

> Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

Nuremberg Code at paragraphs 1, 3, 4 and 6.

85. Defendant Dow Corning Corporation violated each of the aforesaid provisions of the Nuremberg Code in that:

a. Dow Corning Corporation failed to make known to plaintiffs and the putative class members that no adequate human testing had ever been conducted; and that by marketing the silicone gel breast implants without adequate human testing, Dow Corning Corporation and Dow Corning Wright were, in effect, conducting a gigantic human experiment on plaintiffs and the putative class without their knowledge or consent.

b. Defendant Dow Corning Corporation conducted some animal tests on silicone gel and silicone gel breast implants; however, the results of those animal studies did not justify experiments on human beings. Furthermore, many of the animal experiments yielded negative or adverse results; which Dow Corning Corporation did not reveal to plaintiffs or the putative class members.

c. Dow Corning Corporation had absolute knowledge that the use of silicone gel breast implants would cause unnecessary physical and mental suffering and injury in some persons;

however, Dow Corning Corporation nonetheless, continued the experiment on plaintiffs and the putative class. Furthermore, Dow Corning Corporation did not disclose the risks of unnecessary physical and mental suffering and injury as required by the Nuremberg Code.

d. Dow Corning Corporation did not make adequate preparation to protect plaintiffs and the putative class from the possibility of injury, disability and death as required by the Nuremberg Code.

86. By reason of Dow Corning Corporation's violations of the Nuremberg Code, plaintiffs and the putative class have been surgically implanted with silicone gel breast implants that have never been fully tested on animals or human beings. Therefore, plaintiffs and the putative class members have been injured in that they have, without their consent, suffered physical pain, emotional distress and expenses of surgery and hospitalization. Moreover, plaintiffs and the putative class members have become unwitting subjects of a gigantic and dangerous experiment on human beings. By reason of such injuries plaintiffs and the class members they represent should be entitled to money damages; and in addition, they should be entitled to invoke the provisions of paragraph 9 of the Nuremberg Code which states:

> During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he [or she] has reached the physical or mental state where continuation of the experiment seems to him [or her] to be impossible.

87. The defendant's violations of the Nuremberg Code were done with reckless disregard for the rights and safety of the representative plaintiffs and putative class members. Furthermore, the defendant's failure to fully disclose the information, risks and lack of safety studies on their implants prevented the representative plaintiffs and putative class members from discovering the unlawful human experimentation until within the past year, nor could they have discovered or been obliged to try to discover such through their own diligence at any time sooner.

COUNT XIV

VIOLATIONS OF THE MAGNUSON-MOSS WARRANTY ACT

88. Plaintiffs reallege each and every paragraph and allegation above as if fully set forth herein.

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

IN RE CONNIE ALBRECHT, et al.,	)	
Petitioners,	)	No. _____

PETITION FOR WRIT OF MANDAMUS

ROBERT J. DEBRY & ASSOCIATES
ROBERT J. DEBRY, Esq. (A0849)
DEBRA A. ROBB (A5629)
4252 South 700 East
Salt Lake City, UT 84107
Telephone: (801) 262-8915

WALLACE R. BENNETT, Esq. (A0286)
1723 South 2100 East
Salt Lake City, UT 84108
Telephone: (801) 581-1516

D. FRANK WILKINS, Esq. (A3468)
BERMAN, GAUFIN & TOMSIC
50 South Main, #1250
Salt Lake City, UT 84144
Telephone: (801) 328-2200

DAVID D. BENNETT, Esq. (A5917)
SCIENCE & LAW RESEARCH INST.
633 South 800 East
Salt Lake City, UT 84102
Telephone: (801) 521-4065

The petitioners, pursuant to 28 U.S.C. § 1651 and Rule 21(a) of the Federal Rules of Appellate Procedure, apply for a writ of mandamus directing the Honorable Samuel C. Pointer, Judge of the United States District Court for the Northern District of Alabama, Southern Division: (1) to vacate his order (copy attached as Exhibit 1) denying class action status to the petitioners; (2) to hold an evidentiary hearing on the petitioners' motion for class certification; and (3) to enter findings in support of any subsequent decision of the petitioners' Motion for Class Certification. In support of this application, the petitioners state:

III.

ORDER ENTERED BELOW

On July 12, 1993, the respondent, without the benefit of notice or hearing, entered an order denying class action certification to the petitioners. A copy of the order is attached as Exhibit 1.

IV.

STATEMENT OF THE FACTS NECESSARY TO AN UNDERSTANDING OF THE ISSUES PRESENTED IN THIS APPLICATION

The facts necessary to an understanding of the issues presented in this application follow:

A. The Utah Action.

The petitioners are 123 women who each received silicone breast implants supplied by Dow Corning Corp. The petitioners filed their lawsuit, as a class action, in the United States District Court for the District of Utah in October of 1992. The Utah action is titled Albrecht, et al. v. McGhan Medical Corp., et al.

(hereafter Albrecht). The petitioners seek to represent a nationwide class of approximately one million similarly situated women. A copy of the petitioners' Motion for Class Certification with Supporting Memorandum is attached as Exhibit 2.

Before a hearing could be held on the petitioners' motion to certify the class, the case was transferred to the United States District Court for the Northern District of Alabama, Southern Division, pursuant to 28 U.S.C. § 1407.

B. The Ohio Action.

A parallel suit was filed in the United States District Court for the Southern District of Ohio, Western Division under the name of Donna Dante, et al. v. Dow Corning Corp., et al (hereafter, Dante). The Ohio case was also filed as a class action. However, unlike the Utah action, the Ohio court had time to hold hearings on class certification before the case was transferred. A nationwide class was certified by the Ohio court. (See Exhibit 3.) Thereafter the case was transferred to the Northern District of Alabama pursuant to 28 U.S.C. § 1407.

C. The Multi-District Action.

As noted, above, the Utah action (Albrecht) and the Ohio action (Dante) as well as hundreds of other cases throughout the country were transferred to the Northern District of Alabama pursuant to 28 U.S.C. § 1407. Thus, Judge Samuel C. Pointer inherited an amalgamation of breast implant cases from all over the United States, including:

1. A nationwide class action (Dante) which was certified in Ohio before transfer to Judge Pointer;
2. A class action complaint (Albrecht) in which no hearing was held on class certification before transfer to Judge Pointer; and
3. Thousands of individual lawsuits.

D. Distinctive Features of the Utah Action.

In many respects, the Utah complaint (Albrecht) and the Ohio complaint (Dante) are identical. However, the Utah complaint (Albrecht) pleads three distinct causes of action not found in the Ohio (Dante) action. The petitioners seek to have these three unique claims certified pursuant to Rule 23(c)(4)(A).[1]

The first unique aspect of Albrecht is a claim for continuing battery. (Amended Complaint paras. 77-81.) To establish their battery claims, the petitioners need only show an offensive contact. See generally, Restatement (Second) of Torts, §§ 13-20. Moreover, since the breast implants remain in the petitioners' bodies, the battery continues. Finally, the basic measure of damages the petitioners seek is the cost of ending the battery, that is, the cost of removing the implants. (Amended Complaint p. 115 para. 6.)

---

[1] "When appropriate . . . an action may be brought or maintained as a class action with respect to particular issues." Manual for Complex Litigation § 30.17 at 207 (2d Ed. 1986).

The second unique aspect of Albrecht is a claim for unlawful human experimentation. (Amended Complaint paras. 82-87.) The legal foundation for the petitioners' claims is the Nuremberg Code. Basic ethical standards for all human experimentation were declared in the Nuremberg War trials. "[T]he [Nuremberg] code is part of the international law . . . and international law is part of our law. . . ." G.J. Annas, The Law of Informed Consent to Human Experimentation: Preliminary Report Prepared for the National Committee for the Protection of Human Subjects of Biomedical Research, 11 (1976). The Nuremberg Code is also accepted as a basic ethical standard by federal courts. See, United States v. Stanley, 483 U.S. 669, 687 (1987) (J. Brennan, concurring and dissenting); Whitlock v. Duke University, 637 F. Supp. 1463, 1470 (M.D.N.C. 1986); Kaimowitz v. Dept. of Mental Health, 1 Mental Disability L. Rep. 147 (Mich. Cir. Ct. 1973); W.J. Curran, *Legal Codes in Scientific Research Involving Human Subjects*, 34 Lex. Et. Sciemtia, 65 (1966).

The Nuremberg Code explicitly provides:

> The voluntary consent of the human subject is absolutely essential. This means that the person involved . . . should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon

> his health or person which may possibly come from his participation in the experiment.
>
> * * *
>
> The experiment should be so designed and based upon the results of animal experimentation . . . that the anticipated results will justify the performance of the experiment.

(Nuremberg Code at paragraphs 1 and 3.)

The petitioners' complaint alleges that adequate animal tests were not conducted; and that Dow Corning did not reveal all of the known risks and side effects to women who received the breast implants. (Amended Complaint para. 85.) In effect, the petitioners allege that they are subjects of mass human experimentation.

The Nuremberg Code also provides the appropriate remedy:

> During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he [or she] has reached the physical or mental state where continuation of the experiment seems to him [or her] to be impossible.

(Nuremberg Code at paragraph 9.)

Under the Nuremberg Code theory, the petitioners seek a mandatory affirmative injunction requiring Dow Corning to inform all recipients of Dow Corning breast implants of the known risks and side effects. After being fully informed, each woman will have an opportunity, at her election, to "bring the experiment to an end" by having the implants removed at Dow Corning's expense.

The third unique aspect of Albrecht is a claim under the Magnusson-Moss[2] Warranty Act. (Amended Complaint paras. 88-103.) The petitioners claim that Dow Corning breached the implied warranty as defined in 15 U.S.C. § 2301(7) and express warranties as defined in 15 U.S.C. § 2301(6). Unlike the class claims in Dante, the petitioners also claim attorneys' fees under 15 U.S.C. § 2310(d)(2).

The differences between the Dante complaint and the Albrecht complaint are more than theoretical. There are monumental practical differences! To begin with, the Dante complaint covers women who have received some bodily injury from the implant. However, many women have not yet suffered a bodily injury. Rather, they want to get the breast implant out before the injury occurs. The Albrecht class action would cover the latter group.[3] Moreover, in order to win their claims, each plaintiff in the Dante class action must prove that the breast implant caused their bodily injury. This causation issue is very difficult indeed. However, causation is not a necessary element to make out a cause of action

---

2

Frank E. Moss, co-author of the Magnusson-Moss Warranty Act is a member of the attorney team in Albrecht.

3

The Albrecht complaint also includes some women who claim actual bodily injury. The petitioners do not seek to certify those injury claims as a class action. Rather, the injury claims would be subsumed under the Dante class. See generally p. 2 and 3, above.

for battery or violation of the Nuremberg Code. In short, the Albrecht claims are simply easier to prove at trial.

E. Proceedings in the Northern District of Alabama.

Upon receiving the breast implant litigation, Judge Pointer requested the litigants to identify motions that should be ruled upon early in the litigation. In response to Judge Pointer's order, the petitioners notified the Court that there was a pending motion to certify the Albrecht (Utah) lawsuit as a class action. The petitioners requested a hearing on their motion. (Exhibit 4.)

However, Judge Pointer did not hold a hearing on the petitioners' motion to certify the class action. Instead, without any notice, without any arguments, and in a bench conference with other counsel, the Court made the following ruling from the bench:

THE COURT: The very first one is Albrecht v. McGhan motion for class certification is 92-11104. There's an effort to certify a class for certain claims based upon battery and violations of the Nuremberg Code.

VOICE: Your Honor.

THE COURT: Before you say anything, I am going to deny the motion for class certification.

(Laughter)

THE COURT: To the extent that these are appropriate claims and to the extent we're going to have a class, I can deal with it in other litigation without the need to utilize this particular device for certain of these limited theories of action.

Transcript of Proceedings of January 2, 1993, p. 161, lns. 17-25; p. 162, lns. 1-4.[4]

Being unaware that the Court had even made such a bench ruling, the petitioners' counsel again requested a hearing (Exhibit 6). However, the Court did not hold the requested hearing, and in a one sentence order ruled:

> "Plaintiffs' Motion for Class Certification is hereby denied."

Order No. 11, entered May 25, 1993. (See Exhibit 7.)

Because of the perfunctory nature of the May 25 order (Exhibit 7), the petitioners filed a "Motion that Findings of Fact and Conclusions of Law be Entered." (Exhibit 8.) Again, no hearing was held, but the Court entered a new order stating:

> Plaintiff's motion that findings of fact and conclusions of law be entered is hereby GRANTED. The court CONCLUDES that to the extent that a class action will be utilized, the claims stated by the plaintiff on behalf of all women without bodily injuries can be dealt with most efficiently in other existing litigation rather than through a separate class action for these limited causes of action. Consequently, the motion for class certification is DENIED. (Exhibit 1.)

The petitioners file this application to compel the lower court to hold a hearing and to enter meaningful findings on the petitioners' motion to certify the class.

---

[4] A copy of the transcript is attached as Exhibit 5.

V.

ISSUES PRESENTED

The issues presented by this application are:

1. Whether the district court has a mandatory duty to conduct an evidentiary hearing on class certification when, as in this case: (a) all Rule 23 requirements are apparently met; (b) the court denies certification on a ground which is not specified in F.R.C.P. 23; (c) the moving parties have not had an opportunity to address the ground identified by the district court for its decision denying class certification; and (d) as a practical matter the parties are denied the opportunity to litigate the ground used by the district court to deny certification?

2. Whether the district court has a mandatory duty to enter meaningful findings on its class certification ruling?

3. If the duties exist, will mandamus issue to compel the required hearings and findings?

VI.

RELIEF SOUGHT

The petitioners seek a writ of mandamus directing the lower court to: (1) vacate the order denying class action certification; (2) hold an evidentiary hearing on the petitioners' motion for class certification; and (3) enter findings of fact and conclusions of law on the subsequent certification ruling.

VII.

REASONS WHY THE WRIT OF MANDAMUS SHOULD ISSUE

A. Under the Circumstances That Exist in This Case the District Court Had a Mandatory Duty to Conduct an Evidentiary Hearing on the Petitioners' Motion to Certify the Class.

1. The district court, as part of its responsibility to manage the class action litigation, has a duty to hold a hearing on class action certification.

The district court has the responsibility, independent of the litigants, to conduct and manage complex class action litigation. Morrison v. Booth, 730 F.2d 642, 644 (11th Cir. 1984); Ezell v. Mobile Housing Board, 709 F.2d 1376, 1380 (11th Cir. 1983). This responsibility includes the duty to hold an evidentiary hearing on the propriety of the litigation proceeding as a class action. Morrison, supra at 643-644. See Ezell, supra at 1380. The court is required to conduct an evidentiary hearing with or without a motion from counsel. Satterwhite v. City of Greenville, 578 F.2d 987, 993 n. 7 (5th Cir. 1978). The court has an independent duty to hold the certification hearing as early as practicable. Cruz v. Hauck, 627 F.2d 710, 716 (5th Cir. 1980).

2. The Rule 23 criteria for certifying the class requires an evidentiary hearing when there is any doubt as to the propriety of certifying the class.

Rule 23 of the Federal Rules of Civil Procedure requires the petitioners to satisfy the well known touchstones of numerosity, commonality, typicality and adequate representation. Federal Rules of Civil Procedure 23(a)(1-4). In addition, the petitioners must satisfy at least one of the elements of Rule 23(b). These issues, for the most part, are factual issues. See Sirota v. Solitron

Devices, Inc., 673 F.2d 566, 571 (2d Cir. 1982) (numerosity, typicality, commonality).

To resolve the Rule 23 issues, the court first examines the complaint. In those rare cases where it is obvious that the Rule 23 requirements exist or do not exist, the district court may so rule based on the complaint.[5] E.g., Lewis For and On Behalf of Lewis v. Heckler, 752 F.2d 555, 557 (11th Cir. 1985); Bradford v. Sears, Roebuck and Co., 673 F.2d 792, 795-96 (5th Cir. 1982). However, if there is any doubt as to the propriety of a class action, the district court is required to conduct an evidentiary hearing. Morrison, supra at 643-44; Bradford, supra at 796; see Madison v. Miss. Medicaid Comm'n, 86 F.R.D. 178, 185 (N.D. Miss. 1980). Simply put, the lower court should not deny class certification without providing the plaintiff an evidentiary hearing if it is requested. Marcera v. Chinlund, 565 F.2d 253, 255 (2d Cir. 1977).

3. A hearing is required when the district court bases its decision on something other than the Rule 23 criteria.

The district court's duty to hold an evidentiary hearing is mandated when, as here, the court does not base its denial on a

---

5

"[T]he class determination generally involves considerations that are enmeshed in the factual and legal issues comprising the plaintiff's cause of action. (Citations omitted.) Sometimes the issues are plain enough from the pleadings . . . and sometimes it may be necessary to probe behind the pleadings before coming to rest on the certification question." General Telephone Co. of the Southwest v. Falcon, 457 U.S. 147, 160 (1982).

failure to meet Rule 23 requirements. Morrison, supra at 644. In this case, the lower court concluded, without a hearing, that the petitioners' claims can be better managed in existing litigation. However, a well developed factual record is particularly important where class certification is challenged on the asserted ground that, in cases like this one, the proposed class action is unmanageable or can be managed better in some other litigation. Bryant v. Food Lion, Inc., 774 F.Supp. 1484, 1495 (D.S.C. 1991). As explained by the Courts of Appeals for the Third and Fourth Circuits:

> 'Before a ruling is made denying class action certification . . . hard data should be presented to the district court as to the actual difficulty - or ease - involved in determining class membership and managing the class proceeding.' Windham v. American Branch, Inc., 565 F.2d 59, 64 n. 5 (quoting Neeley v. United States, 546 F.2d 1059, 1071 (3d Cir. 1976).

In this litigation there is no hard data supporting or discrediting the lower court's conclusion that the petitioners' claims "can be dealt with more efficiency in other existing litigation." (Exhibit 1.) There is no data because the court failed to perform its mandatory duty of holding a hearing.

For example, the lower court ruled that the class claims in Albrecht (viz. battery and Nuremberg Code violations) " . . . can be dealt with most efficiently in other existing litigation . . ." (See Exhibit 1. Emphasis added.) However, it is not clear what "other existing litigation" the Court is talking about. Nor is it clear why it is more efficient to resolve these claims in the "other existing litigation."

4. A hearing is mandatory if there is a substantive certification issue and without a hearing the moving party, will be denied the opportunity to litigate it.

The fundamental concepts of notice and an opportunity to be heard apply to class action certification proceedings. In re Temple, 851 F.2d 1269, 1272 (11th Cir. 1988). A hearing is mandatory in situations where, as here, there are substantive certification issues and the moving party will be denied an opportunity to litigate it. E.g., Temple, supra; Falcon v. General Telephone Co. of Southwest, 626 F.2d 369, 374 (5th Cir. 1988).

The fundamental certification issue identified by Judge Pointer in this case is manageability. (See Rule 23(b)(3).) As set forth in the Statement of Facts section, the petitioners' claims in the Utah (Albrecht) action are separate and distinct from the claims which have been certified in the parallel Ohio (Dante) class action litigation. "Differences in claims can create conflicts in pre-trial, trial and settlement." J.W. Moore, Manual for Complex Litigation § 30.16 at 205, 206 (2 Ed. 1986). In addition, the relief sought by some claimants often competes with relief sought by others. Id. In this case, the petitioners seek injunctions to end the unlawful batteries and experiments. Injunctive relief is not sought in the parallel Dante litigation. The appropriate remedy for substantial differences is to create the subclass requested by the petitioners. See id. However, by declining to notify the petitioners in advance of its ruling and by declining to hold a hearing, the district court

precluded the petitioners from ever litigating the manageability and conflicts issues.[6]

B. The District Court Has a Mandatory Duty to Make and Enter Findings in Support of Its Certification Decision.

1. The lower court did not make any meaningful findings.

As set forth in page 11 of this petition, the class certification issues raised by Rule 23 are mostly factual issues. The Court, by order, determines whether a case qualifies as a class action. Federal Rules of Civil Procedure 23(c). When the Court rules upon such factual issues, Rule 52(a) of the Federal Rules of Civil Procedure requires the district court to "find the facts specially and state separately its conclusions of law thereon." The duty to make the findings required by Rule 52 is mandatory. E.g., H. Prang Trucking Co., Inc. v. Local Union No. 469, 613 F.2d 1235 (3d Cir. 1980); see United States By Clark v. Gramer, 418 F.2d 692, 693 (5th Cir. 1969) and it applies to certification proceedings.

> The judge should enter findings and conclusions after the hearing, addressing each of the applicable requirements of Rule 23(a) and (b).

Manual for Complex Litigation, supra § 30.13 at 202.

In determining whether a lawsuit should proceed as a class action, the district court must make findings on each essential

---

[6] See footnote 1, above.

element specified in Rule 23.[7] E.g., Bradford v. Sears, Roebuck and Co., 673 F.2d 792 (5th Cir. 1982); Price v. Lucky Stores, Inc., 501 F.2d 1177, 1179 (9th Cir. 1974); Beebe v. Pacific Realty Trust, 99 F.R.D. 60, 64 (D. Ore. 1983).

In this case, the district court did not make a finding on each of the Rule 23 elements. It did not make a finding at all. All it did, was make a one sentence conclusion that this litigation could be more efficiently handled with other class action litigation.

Rule 52 is not satisfied by a statement of ultimate fact. E.g., H. Prang Trucking, supra; Smith v. Dental Products Co., 168 F.2d 516, 518 (7th Cir. 1948). Most of the Circuits require that the district court's finding on the ultimate issue of fact be supported by subsidiary fact findings. See e.g., O'Neil v. United States, 411 F.2d 139, 146 (3d Cir. 1969); McIntosh County Branch of NAACP v. City of Darien, 605 F.2d 753, 757 (5th Cir. 1979); Deal v. Cincinnati Board of Education, 369 F.2d 55, 64 (6th Cir. 1966); Kweskin v. Finklestein, 223 F.2d 677 (7th Cir. 1951); Van Borg, Allen, Weinberg and Rogers v. N.L.R.B., 656 F.2d 1356 (9th Cir. 1981); and Wood's Construction Co. v. Pool Construction Co., 314 F.2d 405 (10th Cir. 1963).

---

[7] A court's resolution of the class action issue is not entitled to the deference due such a determination when it is supported by findings as to the application of Rule 23 criteria. Gibson v. Local 40 Supercargoes & Checkers, etc., 543 F.2d 1259, 1263 n.2 (9th Cir. 1976).

When the district court fails to comply with the letter and spirit of Rule 52(a), the remedy is to remand for compliance. E.g., Lemelson v. Kellogg Co., 440 F.2d 986 (2d Cir. 1971); Squirt Co. v. Seven Up Co., 628 F.2d 1086 (8th Cir. 1980).

2. The one unsupported finding or conclusion the court did make is of no consequence.

The trial court entered a one sentence conclusion that the class claims in Albrecht can be more efficiently handled in other litigation. Apparently that lone finding relates to Rule 23(b)(3).[8]

However, the Court's sole conclusion is of no consequence. It doesn't matter whether the petitioners make the showing required by Rule 23(b)(3) because they clearly meet the requirements of Rule 23(b)(2). As set forth in page 11 of this application, after the petitioners satisfy the Rule 23(a) requirements, they need only satisfy one of the Rule 23(b) requirements.

In summary, it simply makes no difference whether or not the class claims (viz. battery and Nuremberg Code) in Albrecht can be

---

[8] "[T]he court finds that the questions of law or fact common to the members of the class predominate over any questions affecting only individual members, and that a class action is superior to other available methods for the fair and efficient adjudication of the controversy. The matters pertinent to the findings include: (A) the interest of members of the class in individually controlling the prosecution or defense of separate actions; (B) the extent and nature of any litigation concerning the controversy already commenced by or against members of the class; (C) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; (D) the difficulties likely to be encountered in the management of a class action."

more efficiently handled in other existing litigation because that is a Rule 23(b)(3) consideration. Since the class can and should be certified under Rule 23(b)(2), the Court has no reason to make Rule 23(b)(3) findings.

C. Mandamus Should Issue to Order the Required Hearing and Findings.

Mandamus has traditionally been used to compel inferior courts to exercise their authority when it is their duty to do so. E.g., Will v. United States, 389 U.S. 90, 95 (1967); In re Smith, 926 F.2d 1027 (11th Cir. 1991). The writ is issued in exceptional circumstances or extraordinary situations.[9] Schlagenhauf v. Holder, 379 U.S. 104, 110-11 (1964); In re Fink, M.D., 876 F.2d 84 (11th Cir. 1989); In re Smith, 926 F.2d 1027, 1030 (11th Cir. 1991); In re Paradyne Corp., 803 F.2d 604, 612 (11th Cir. 1986).

In Bauman v. United States Dist. Court, 557 F.2d 650 (9th Cir. 1977), the Court of Appeals for the Ninth Circuit developed five guidelines or factors to determine whether a class action certification proceeding will be corrected by issuing a writ of mandamus. First, the party seeking the writ must lack other adequate means, such as a right of direct appeal, to obtain the desired relief. The second related factor is whether the petitioners will be damaged or prejudiced in a way not correctable on appeal.

---

[9] An issue is extraordinary if it is novel or not authorized by any rule. Pan Am World Airways, Inc. v. U.S. Dist. Ct., C.D. Cal., 523 F.2d 1073 (9th Cir. 1975).

The third guideline is whether the district court's order is clearly erroneous. The fourth factor is whether an oft-repeated error occurred or whether the district court manifested a disregard of the federal rules. The fifth factor is whether the certification order raises new and important problems or issues of first impression. Id. at 652-653. The Ninth Circuit emphasized that:

> [R]arely, if ever, will a case arise where all the guidelines point in the same direction or even where each guideline is relevant or applicable. The considerations are cumulative and proper disposition will often require a balancing of conflicting indicators.

Bauman at 655.

The Ninth Circuit's five guidelines are accepted by the Courts of Appeal for the Sixth and Tenth Circuits. See In re Bendectin Products Liability Litigation, 749 F.2d 300 (6th Cir. 1984); In re Dalton, 733 F.2d 710, 716-717 (10th Cir. 1984).

This Court adopted the Bauman analytical framework in In re Temple, 851 F.2d 1269, 1270-71 (11th Cir. 1988). Like the lower court in this case, the district court in Temple, failed to conduct a hearing before making a decision on class certification. As in this case, the district court also failed to notify the petitioners that the court was going to rule on whether the case should proceed as a class action. Because the lower court failed to hold a hearing, this Court rejected the district court's speculative finding that there existed a limited fund. The Court explained:

> The Court's failure to notify petitioners of the certification hearing denied them due process.
>
> * * *

> The non-adversarial nature of the proceeding below almost certainly led to the premature and speculative finding that a limited fund existed. . . . Without a finding as to the net worth of the defendants, it is difficult to see how the fact of a limited fund could have been established. . . . Had Raymark's motion been contested, such a salient fact would most certainly have been addressed.

Temple at 1272.

The Court of Appeals remedied the error by issuing a writ of mandamus vacating the court's order. Temple at 1272.

Temple squarely applies to this case. The errors committed by the district court in Temple are identical to the errors committed by the district court in this case. Both courts denied the petitioners due process by failing to notify them of the class certification proceedings. Both courts failed to conduct an evidentiary or adversarial proceeding. Both courts made a speculative conclusion. Temple dictates that mandamus be issued vacating the lower court's order and ordering a class certification hearing.[10]

---

[10] Application for the five guidelines enumerated in Bauman and accepted by the Court of Appeals for the 11th, 10th and 6th Circuit also leads to the same result. The petitioners have no other remedy. They cannot appeal the certification order under 28 U.S.C. § 1291 or 1292. Temple at 1270; Green v. Occidental Petroleum Corp., 541 F.2d 1335 (9th Cir. 1975). The district court's failure to hold the hearing and make findings was clearly erroneous. Temple, supra; see Dalton, supra (failure to follow Rule 23 criteria is clearly erroneous). This court's prior decisions in Morrison, supra, and Temple, supra illustrate that the failure to hold a class certification hearing is an oft-repeated error. Moreover, the court's failure to consider the criteria set forth in Rule 23 shows the court's failure to abide by the Federal Rules of Civil

See also, In re Bendectin Products Liability Litigation, 749 F.2d 300, 306 (6th Cir. 1984) (class order vacated where the petitioners were given no opportunity to dispute the unsupported finding adopted by the district court); A.H. Smith Sand & Gravel Co., v. Dept. of Water Resources, 313 A.2d 820, 826 (Md. App. 1974) (writ of mandamus may be issued to compel a hearing); Burnett v. Superior Court of Orange County, 528 P.2d 372 (Cal. 1974) (writ of mandamus proper to compel court to hear a motion); MAI Equipment Corp. v. Brooke, Mayo & Derrick, 263 So.2d 419, 420 (La. App. 1972) (the remedy for a refusal to file reasons for a judgment after a request to do so is an application for writ of mandamus); Pan Am World Airways, Inc. v. U.S. Dist. Ct., C.D. Cal., 523 F.2d 1073 (9th Cir. 1975) (inappropriate notice); McDonnell Douglas Aircraft Corp. v. United States District Court, 523 F.2d 1083 (9th Cir. 1975) (clearly erroneous certification decision corrected by mandamus); Green v. Occidental Petroleum Corp., 541 F.2d 1335, 1340 (9th Cir. 1975) (mandamus issued to correct erroneous application of the criteria set forth in Rule 23(b)(1)); Katz v. Carte Blanche Corp., 496 F.2d 746, 752 (3d Cir. 1973) (certification order may be reviewed by mandamus if the district court has acted without appropriate procedural safeguards).

Procedure. By effectively allowing only one national class, the lower court created important problems of competing claims and relief. This is one of the rare cases when all the guidelines are relevant and point toward granting mandamus. See Bauman, supra.

WHEREFORE, the petitioners pray that a writ of mandamus be issued by this Court to the Honorable Sam C. Pointer vacating his Order Denying Class Action Certification and directing the Court to hold an evidentiary hearing on the petitioners' Motion for Class Action Certification, and to make appropriate findings as a result from the hearing process.

VIII.

EXHIBITS

The exhibits attached to this application are: 1) Order Denying Class Action, July 12, 1993; 2) Petitioners' Motion and Memorandum in Support of Class Certification of Counts XII, XIII and XIV, October 28, 1992; 3) Order Certifying Class Certification and Order Confirming and Amending Class Certification in the Dante v. Dow Corning, et al. Case, February 14, 1992; 4) Robert J. DeBry Letter to Honorable Samuel C. Pointer Requesting a Hearing on Motion, October 30, 1992; 4) Transcript of Proceedings, January 2, 1993; 5) Robert J. DeBry Letter to Honorable Samuel C. Pointer Requesting a Hearing on Motion, April 29, 1993; 6) Order Denying Class Certification, May 25, 1993; 7) Petitioners' Motion that Findings of Fact and Conclusions of Law be Entered, June 22, 1993; and 8) Albrecht Second Amended Complaint, September 10, 1993.

DATED this 11 day of February, 1994.

ROBERT J. DEBRY

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

In re: SILICONE GEL BREAST IMPLANT PRODUCTS LIABILITY LITIGATION MDL 926	)	Master File No. CV-92-P-10000-S
This Agreement relates to: ALL ACTIONS.	)	
HEIDI LINDSEY, et al, on behalf of themselves and all others similarly situatated, Plaintiffs, v. DOW CORNING CORPORATION, et al. Defendants.	)	Case No. CV-94-P-11558-S Honorable Sam C. Pointer, Jr.

BREAST IMPLANT LITIGATION
SETTLEMENT AGREEMENT

constitute or be deemed to constitute a waiver by Defendants or Release parties of defenses based on statutes of limitations or repose with respect to any Settlement Class Member who opts out of this Agreement during the First or Second Opt Out Periods and whose claim was barred by the applicable statues of limitations or repose as of the date of execution of this Agreement.

B. Monetary Terms/Establishment Of Settlement Fund.

4. Subject to all of the conditions contained in this Agreement, and in accordance with the terms and conditions of the Funding Agreement, the Defendants shall be obligated to pay up to the aggregate Maximum Settlement Amount set forth in the Funding Agreement in consideration for this Agreement. Each Defendant's obligation to pay under this Agreement is limited to the obligations set forth in the Funding Agreement (attached hereto as Exhibit C), and set forth in the Schedules of Defendant's Payments (attached hereto as Exhibit D).

5. All monies due and owing by Defendants under this Agreement shall be paid when due under the Funding Agreement by wire transfer in to a "Settlement Fund" to be established, maintained, invested, and administered by Settlement Class Counsel under the continuing jurisdiction and supervision of the Court. The assets of the Settlement Fund shall be invested, in the discretion of Settlement Class Counsel, in a manner intended to achieve maximum earnings consistent with safety and appropriate liquidity to pay claims without undue delay. Any and all interest

and earnings of the Settlement Fund assets shall accumulate and become part of the Settlement Fund

6. Except as specifically set forth in Sections V and XIX of this Agreement and in the Funding Agreement, Defendants and Released Parties shall have no ownership or reversionary interest in the Settlement Fund. Defendants and Released Parties shall have no interest in or responsibility for allocations or distributions therefrom and do not guarantee any earnings from any portion of the Settlement Fund assets that may be invested to generate income to satisfy claims.

7. Each Defendant shall be responsible and liable only for its individual obligations under this Agreement and under the Funding Agreement. Defendants' obligations under this Agreement and the Funding Agreement are not intended to and shall not create nor be deemed to create any joint or joint and several obligation on the part of the Defendants and Released Parties.

C. **Establishment Of Designated Funds And Disease Compensation Program For The Benefit Of Settlement Class Members**

The Settlement Amounts paid by the Defendants shall be used: (1) to establish and fund the Designated Funds as specified in this Agreement; and (2) to establish and fund the Disease Compensation Program. The assets of the Designated Funds and the Disease Compensation Program shall be used for the benefit of the Settlement Class. Settlement Class Members' inability, notwithstanding reasonable efforts, as determined by the Claims

Administrator, to identify the manufacturers of their Breast Implants shall not affect their status as Eligible Claimants.

1. Designated Funds.

The Designated Funds I-V described below shall be established with an amount aggregating approximately 16.8% of the aggregate Maximum Settlement Amounts to be paid by the Signatory Defendants under the Funding Agreement. The Notice shall advise Settlement Class Members of the amounts initially allocated by Settlement Class Counsel to Funds I-V, and by the Court to Fund VI. Each Designated Fund shall be used for the purposes described below, subject to the power, as described in Section III.F. below, to reallocate the assets of the Designated Funds as necessary and appropriate to ensure fairness to Eligible Claimants, and subject to the funding requirements to Fund VI to implement the Court's orders regarding costs, fees and expenses. Except as otherwise provided, Settlement Class Members may be eligible for payments from more than one Fund and for payments from the Disease Compensation Program. Criteria for eligibility, allocation and distribution of each of the Designated Funds shall be subject to Court approval.

a. Fund I – Medical Diagnostic/Evaluation Fund.

Fund I shall be established for the purpose of paying certain Unreimbursed Costs for medical diagnoses and evaluations with respect to Included Breast Implant Related medica problems on an ongoing basis, and to provide information for the benefit of Claimants. Recipients of payments from Fund I shall assign their

rights of reimbursement against third parties to the Settlement Fund, which would be entitled to seek reimbursement as assignee. Third parties shall not be entitled to seek reimbursement from this Fund.

All Eligible Claimants who are living Breast Implant Recipients may make application for payment of or reimbursement for medical evaluations and diagnoses pursuant to guidelines and payment schedules to be determined by Settlement Class Counsel and approved by the Court. Settlement Class Counsel may, in their discretion, establish one or more experienced practitioners or researchers to serve as medical evaluation advisors who may provide advice and assistance for the benefit of the evaluating doctors and their patients. Costs associated with the establishment and maintenance of such advisors shall be paid from the assets of Fund I.

b. **Fund II - Explantation Fund.**

Fund II shall be established to pay or reimburse Eligible Claimants for certain Unreimbursed Costs associated with explantation of Breast Implants and related necessary surgery. Guidelines for eligibility for and amounts of individual payments to Eligible Claimants from Fund II shall be determined by Settlement Class Counsel and approved by the Court. Claimants shall not be reimbursed for the cost of any surgery performed to implant any Breast Implants after June 1, 1993, or for the removal of any Breast Implants implanted after June 1, 1993.

c. Fund III - Rupture Fund.

Fund III shall be established to provide payment to Eligible Claimants who have had one or more ruptures of an Included Breast Implant and who are not Eligible Current Claimants under the Disease Compensation Program. Guidelines for eligibility for compensation from Fund III, and the schedule of payments to rupture claimants, will be determined by Settlement Class Counsel and approved by the Court.

d. Fund IV – Breast Implant Recipient Compensation Fund.

Fund IV shall be established to provide payment to Eligible Claimants who are not Eligible Current Claimants under the Disease Compensation Program, and who do not qualify for a payment under Fund III (Rupture Fund). Claimants who meet these criteria are eligible to receive a share of this fund as determined by Settlement Class Counsel and approved by the Court.

e. Fund V - Reserve Fund.

Fund V shall be established as a Reserve Fund to be used as Settlement Class Counsel deems necessary and appropriate under this Agreement for the benefit of Settlement Class Members, subject to Court approval.

f. Fund VI - Settlement Class Costs, Expenses and Fees.

Fund VI shall be established by Court order to fund all costs of settlement notice and claims administration, and to pay such reimbursement of costs and expenses and awards of fees as the

Court may approve to counsel who represent individual Settlement class Members and/or the Settlement Class. Fund VI shall be funded, as directed by the Court, by a specified percentage of the aggregate Settlement Amount and shall not constitute an additional obligation of Defendants. All payments of costs and expenses and awards of attorneys' fees incurred in connection with settlement Class Members' rights and claims under this Agreement shall be subject to Court Approval and, if approved, shall be paid from Fund VI. Payments to Settlement Class Members from the other Designated funds and from the Disease Compensation Program shall be net payments to Eligible Claimants for the purpose of preserving payment parity, such that similarly situated Eligible Claimants shall receive similar amounts without regard to their individual fee agreements with counsel, if any. Settlement Class Members shall have no other attorneys' fees, expenses or cost obligations with respect to benefits under this Agreement and payments form any Designated Fund or from the Disease Compensation Program.

g. **Adjustments in the Event of Withdrawal or Final Default.**

In the event of the withdrawal or Final Default of a Defendant, amounts allocated to the above Funds shall be adjusted in accordance with the provisions of Sections V and XIII of this Agreement.

2. Disease Compensation Program.

The Disease Compensation Program shall be a program under which Eligible Claimants who satisfy the diagnostic criteria set forth in the Disease Definitions shall be entitled to receive payment in accordance with the Disease Compensation Schedule, subject to the procedures and adjustments to the Disease Compensation Schedule prescribed below. The Disease Compensation Program shall be maintained for the Initial Claims Period and a thirty (30) year ongoing period ("the Ongoing Disease Compensation Program").

a. Compensation for Eligible Current Claimants Under the Disease Compensation Program.

(1) Limitation on Aggregate Payment for Current Claimants.

The Initial Payment shall be paid as set forth in the Funding Agreement (Exhibit C hereto) and Schedules of Defendants' Payments (Exhibit D hereto) to fund the Disease Compensation Program for Eligible Current Claimants. If the total dollar amount of Eligible current Claims paid under the Disease Compensation Program is less than the Initial Payment, the unused portion of the Initial Payment shall be applied to pay Eligible Ongoing claims under the Disease Compensation Program, if and when needed as provided in Section III.C.2.b(2)(c) of this Agreement. Application of the unused portion of the Initial Payment to pay Eligible Ongoing Claims shall not reduce the Settlement Amount.

(2) Determination of Payment Amounts.

Each Eligible Current Claimant shall receive a payment as prescribed for the appropriate disease, level of severity, and age category on the Disease Compensation Schedule (Exhibit F hereto). This amount may be adjusted as provided below. Additionally, a percentage to be determined by the Court may be deducted for purposes of funding Fund VI.

EXHIBIT "D"
DOW CORNING CORPORATION FUNDING SCHEDULE
(IN MILLIONS OF DOLLARS)

FUNDING YEAR	ANNUAL FUNDING OBLIGATION	MAXIMUM CUMULATIVE FUNDING OBLIGATION
PRELIMINARY PAYMENT	$42.50	$42.50
YEAR 1	$275.00	$317.50
YEAR 2	$275.00	$592.50
YEAR 3	$275.00	$867.50
YEAR 4	$51.17	$918.67
YEAR 5	$51.17	$969.84
YEAR 6	$51.17	$1,021.01
YEAR 7	$51.17	$1,072.18
YEAR 8	$51.17	$1,123.35
YEAR 9	$51.17	$1,174.52
YEAR 10	$51.17	$1,225.69
YEAR 11	$51.17	$1,276.86
YEAR 12	$51.17	$1,328.03
YEAR 13	$51.17	$1,379.20
YEAR 14	$51.17	$1,430.37
YEAR 15	$51.17	$1,481.54
YEAR 16	$51.17	$1,532.71
YEAR 17	$38.38	$1,571.09
YEAR 18	$38.38	$1,609.47

YEAR 19	$38.38	$1,647.85
YEAR 20	$38.38	$1,686.23
YEAR 21	$38.38	$1,724.61
YEAR 22	$38.38	$1,762.99
YEAR 23	$38.38	$1,801.37
YEAR 24	$38.38	$1,839.75
YEAR 25	$25.57	$1,865.32
YEAR 26	$25.57	$1,890.89
YEAR 27	$25.57	$1,916.46
YEAR 28	$25.57	$1,942.03
YEAR 29	$25.57	$1,967.60
YEAR 30	$25.57	$1,993.17
YEAR 31	$25.57	$2,018.74
TOTALS	$2,018.74	$2,018.74
MAXIMUM SETTLEMENT AMOUNT		$2,018.74

EXHIBIT "D"
BAXTER HEALTHCARE CORPORATION FUNDING SCHEDULE
(IN MILLIONS OF DOLLARS)

FUNDING YEAR	ANNUAL FUNDING OBLIGATION	MAXIMUM CUMULATIVE FUNDING OBLIGATION
PRELIMINARY PAYMENT	$11.70	$11.70
YEAR 1	$152.10	$163.80
YEAR 2	$64.35	$228.15
YEAR 3	$64.35	$292.50
YEAR 4	$11.70	$304.20
YEAR 5	$11.70	$315.90
YEAR 6	$11.70	$327.60
YEAR 7	$11.70	$339.30
YEAR 8	$11.70	$351.00
YEAR 9	$11.70	$362.70
YEAR 10	$11.70	$374.40
YEAR 11	$11.70	$386.10
YEAR 12	$11.70	$397.80
YEAR 13	$11.70	$409.50
YEAR 14	$11.70	$421.20
YEAR 15	$11.70	$432.90
YEAR 16	$11.70	$444.60
YEAR 17	$8.78	$453.38
YEAR 18	$8.78	$462.16

YEAR 19	$8.78	$470.94
YEAR 20	$8.78	$479.72
YEAR 21	$8.78	$488.50
YEAR 22	$8.78	$497.28
YEAR 23	$8.78	$506.06
YEAR 24	$8.78	$514.84
YEAR 25	$5.85	$520.69
YEAR 26	$5.85	$526.54
YEAR 27	$5.85	$532.39
YEAR 28	$5.85	$538.24
YEAR 29	$5.85	$544.09
YEAR 30	$5.85	$549.94
YEAR 31	$5.85	$555.79
TOTALS	$555.79	$555.79
MAXIMUM SETTLEMENT AMOUNT		$555.79

EXHIBIT "D"
MEDICAL ENGINEERING CORPORATION AND BRISTOL-MYERS SQUIBB COMPANY FUNDING SCHEDULE
(IN MILLIONS OF DOLLARS)

FUNDING YEAR	ANNUAL FUNDING OBLIGATION	MAXIMUM CUMULATIVE FUNDING OBLIGATION
PRELIMINARY PAYMENT	$24.30	$24.30
YEAR 1	$315.90	$340.20
YEAR 2	$133.65	$473.85
YEAR 3	$133.65	$607.50
YEAR 4	$24.30	$631.80
YEAR 5	$24.30	$656.10
YEAR 6	$24.30	$680.40
YEAR 7	$24.30	$704.70
YEAR 8	$24.30	$729.00
YEAR 9	$24.30	$753.30
YEAR 10	$24.30	$777.60
YEAR 11	$24.30	$801.90
YEAR 12	$24.30	$826.20
YEAR 13	$24.30	$850.50
YEAR 14	$24.30	$874.80
YEAR 15	$24.30	$899.10
YEAR 16	$24.30	$923.40
YEAR 17	$18.23	$941.63

YEAR 18	$18.23	$959.86
YEAR 19	$18.23	$978.09
YEAR 20	$18.23	$996.32
YEAR 21	$18.23	$1,014.55
YEAR 22	$18.23	$1,032.78
YEAR 23	$18.23	$1,051.01
YEAR 24	$18.23	$1,069.24
YEAR 25	$12.15	$1,081.39
YEAR 26	$12.15	$1,093.54
YEAR 27	$12.15	$1,105.69
YEAR 28	$12.15	$1,117.84
YEAR 29	$12.15	$1,129.99
YEAR 30	$12.15	$1,142.14
YEAR 31	$12.15	$1,154.29
TOTALS	$1,154.29	$1,154.29
MAXIMUM SETTLEMENT AMOUNT		$1,154.29